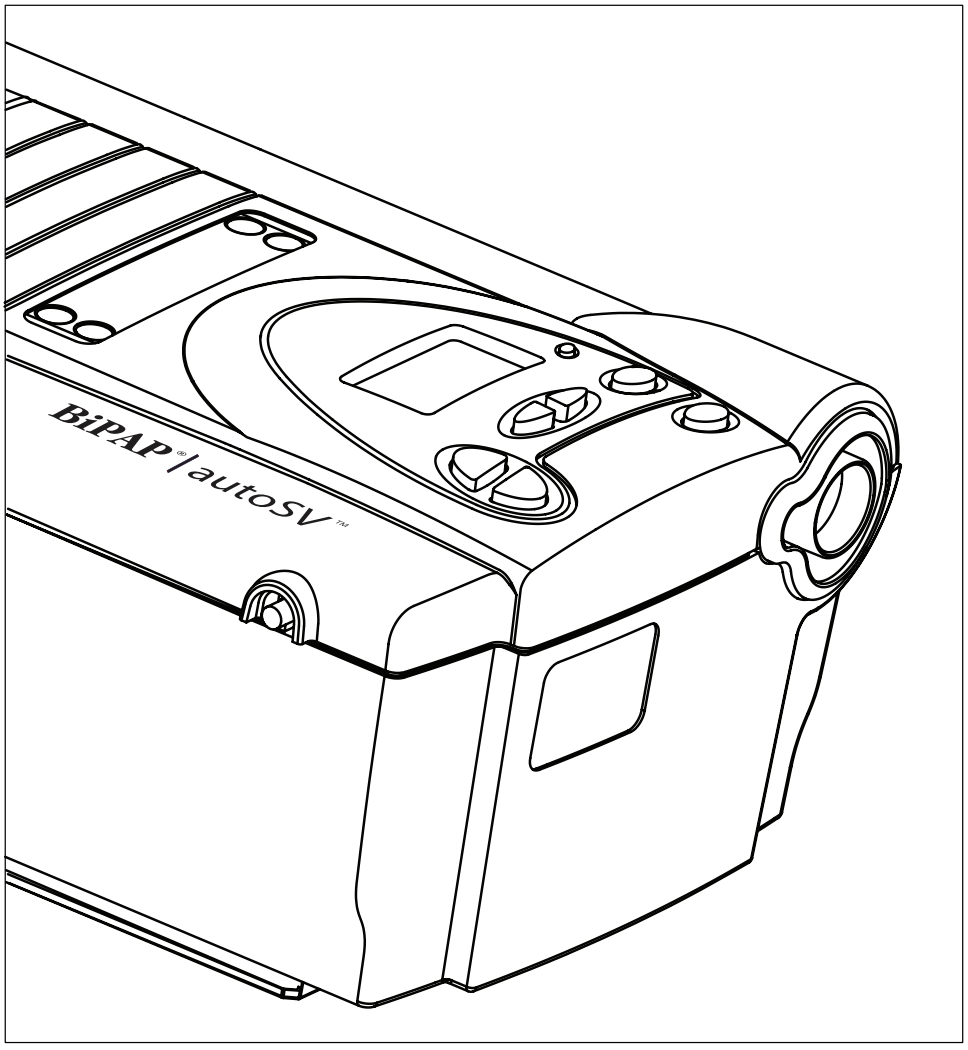
RESPIRONICS®

BiPAP® | autoSV™ with Encore SmartCard®

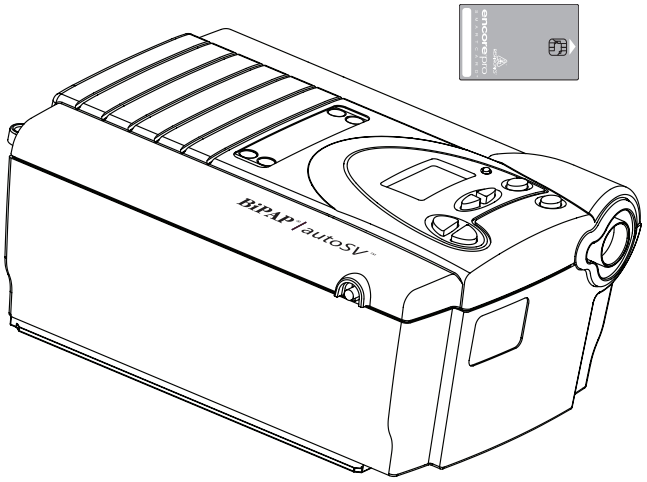


Provider Manual

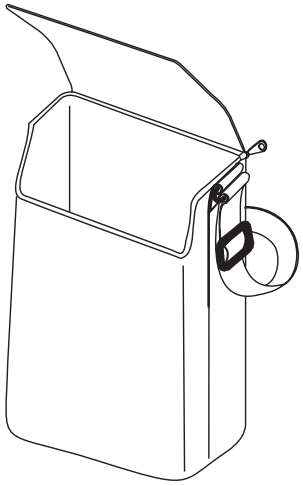
This BiPAP system is covered by one or more of the following patents: U.S. Patent Nos. 5,148,802; 5,239,995; 5,313,937; 5,433,193; 5,632,269; 5,803,065; 6,029,664; 6,305,374 and 6,539,940; Australian Patent Nos. 638054; 661575; 698519; 723681; 734319 and 733655; Canadian Patent Nos. 2,024,477; 2,162,981 and 2,259,795; European Patent No. EP0425092; German Patent No. 69021681.5-08; and Japanese Patent Nos. 2832812; 2137336; and 2926392. Other U.S. and foreign patents pending.

Table of Contents

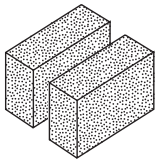
CHAPTER 1: PACKAGE CONTENTS



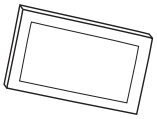
BiPAP autoSV with
Encore® Pro SmartCard™



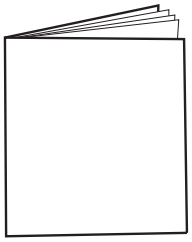
Carrying Case



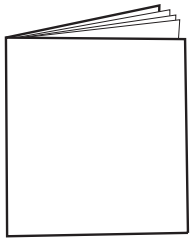
Reusable Gray
Foam Filters



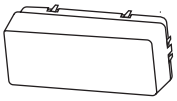
Disposable
Ultra-fine Filter



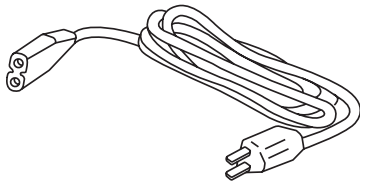
User Manual



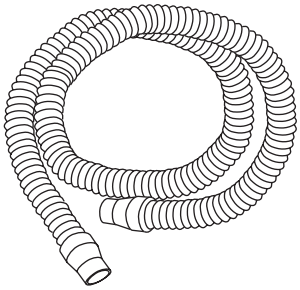
Provider Manual



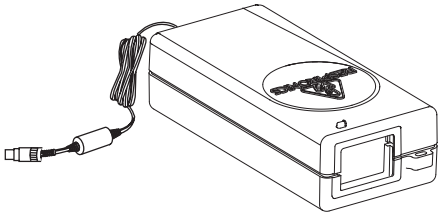
Filter Cap



Power Cord



Flexible Tubing
1.83 m (6 ft.) x 22 mm i.d.



External AC Power Supply

Chapter 2: Warnings and Cautions

WARNING: Indicates the possibility of injury to the patient or the operator.

CAUTION: Indicates the possibility of damage to the BiPAP autoSV device.

NOTE: Places emphasis on an operating characteristic.

Caution: *U.S. federal law restricts this device to sale by or on the order of a physician.*

2.1 Warnings

- This manual serves as a reference. The instructions in this manual are not intended to supersede the instructions of the health care professional. The operator should read and understand this entire manual before using the device.
- Long term effects of the treatment of sleep disordered breathing and/or Cheyne Stokes Respiration in patients with Congestive Heart Failure (CHF) or atrial fibrillation have not been documented. Therefore, caution should be exercised when using this device on a patient with CHF or atrial fibrillation. The clinician should assess the relative risk and benefits of the therapy on a case-by-case basis.
- The device provides positive pressure ventilation and is indicated for assisted ventilation. This system does not provide ventilation with guaranteed tidal volume delivery. Patients requiring ventilation at predetermined tidal volumes are not candidates for pressure support ventilation.
- This is not a life support ventilator. *BiPAP autoSV* is a non-continuous ventilator intended to augment patient breathing. It is not intended to provide total ventilatory support. It may stop operating with power failure or if a fault occurs in the product.
- In the event of a power or device failure, audible and visual alarm signals will activate. The device must then be disconnected from the patient immediately. As is the case with most ventilators with passive exhalation ports, when power is lost, sufficient air will not be provided through the circuit, and exhaled air may be rebreathed.
- At low EPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur. Monitor the patient appropriately.
- To reduce the risk of contamination, you may place a bacteria filter in-line between the device and the patient.
- The device does not have an alarm to detect occlusion of the exhalation port. Before each use, inspect the patient circuit to verify that the port is not occluded. Occlusion or partial occlusion can reduce airflow and result in rebreathing of exhaled air.
- Verify the operation of the Patient Disconnect alarm with any changes in the patient circuit.
- Verify that the Patient Disconnect alarm is active if required for medical reasons.
- If the patient has a severe obstructive or restrictive spirometric defect, or severe daytime hypercapnia or hypoxia, then the device may not be an appropriate treatment method. This is due to the level of ventilatory support that the device provides.
- Do not connect any equipment to the device unless recommended by Respironics or the health care professional. Verify that an exhalation port is present to exhaust CO_2 from the circuit. If circuit accessories other than those recommended by Respironics are connected to the device, then pressure must be verified. Use of these accessories may alter the pressure received, reducing the effectiveness of treatment.
- The device should be used only with masks and accessories recommended by Respironics or with those recommended by the health care professional or respiratory therapist. See Chapter 10 for approved patient circuits. A mask should not be used unless the device is turned on and operating properly. The exhalation port(s) associated with the mask should never be blocked. In the event of a power failure or machine malfunction, remove the mask.

  Explanation of the Warning: The device is intended to be used with special masks or connectors that have exhalation ports to allow a continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask exhalation port. However, when the device is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.

- Operation of the device may be adversely affected by:
  - Electromagnetic fields exceeding the level of 10 V/m in the test conditions of EN 60601-1-2
  - Operation of high frequency (diathermy) equipment
  - Defibrillators, or short wave therapy equipment
  - Radiation (e.g., x-ray, CT)
  - Magnetic fields (e.g., MRI)
- Do not use the device at room temperatures above 95° F (35° C). If the device is used at room temperatures above 95° F (35° C), the temperature of the airflow may exceed 106° F (41° C), which could cause thermal irritation or injury to the patient's airway.
- Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the device.
- Do not use antistatic or electrically conductive hoses or tubing with the device.
- When the device is used with an external humidifier, position the humidifier so that the water level in the humidifier is lower than the patient and the humidifier is on the same level or lower than the device. Use only Respironics-approved humidifiers with the *BiPAP autoSV*.
- If you detect any unexplained changes in the performance of the device, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, seek the assistance of Respironics or an authorized service center.
- Do not open the *BiPAP autoSV* enclosure. There are no user serviceable parts inside. Repairs and internal servicing should only be performed by an authorized service agent.
- Electrical cords and cables should be periodically inspected for damage or signs of wear. Replace any damaged parts before using.
- To avoid electrical shock, unplug the device before cleaning.
- Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used. Precautionary procedures include methods to prevent build-up of electrostatic discharge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and grounding oneself by means of a wrist strap to the equipment or system or to earth.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not in use.

  Explanation of the warning: When the device is not in operation and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device's enclosure. Oxygen accumulated in the ventilator enclosure will create a risk of fire.
- When using oxygen with this system, a Respironics Pressure Valve must be placed in-line with the patient circuit.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- When administering fixed-flow supplemental oxygen, the O_2 concentration may not be constant. The inspired oxygen concentration will vary, depending on the IPAP and EPAP pressures, patient breathing pattern, and the leak rate. Substantial leaks around the mask may reduce the inspired oxygen concentration to less than the expected concentrations. Monitor the patient appropriately.
- To prevent an accumulation of oxygen in the device, advise the patient to turn the device on before turning on the oxygen. Likewise, the patient must turn off the oxygen before turning off the device.
- Do not use the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.

2.2 Cautions

- The device may only be operated at temperatures between 41° F (5° C) and 95° F (35° C).
- Do not immerse the device or allow any liquid to enter the enclosure or the inlet filter.
- Do not place the device in or on any container that can collect or hold water.
- Condensation may damage the device. Always allow the device to reach ambient temperature before use.
- Use the power cable retainer to keep the power cord from being unintentionally disconnected.

NOTE: Additional warnings, cautions, and notes are located throughout this manual.

2.3 Intended Use

The BiPAP autoSV is intended to provide non-invasive ventilatory support to treat adult patients with OSA and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.

2.4 Contraindications

The *BiPAP autoSV* system should not be used on patients with the following conditions:

- Patients without a spontaneous respiratory drive
- Existing respiratory failure (failure to treat; risk of increased work of breathing due either to incomplete reversal of upper airway obstruction or to breathing at high lung volume, leading to worsening respiratory failure)
- Pneumothorax or pneumomediastinum
- Emphysematous bullae or a past history of pneumothorax (risk of pneumothorax)
- Acute decompensated cardiac failure or hypotension, particularly if associated with intravascular volume depletion (risk of further hypotension or reduction in cardiac output)
- Massive epistaxis or previous history of massive epistaxis (risk of recurrence)
- Pneumoencephalus, recent trauma or surgery (e.g., pituitary or nasal) that may have produced cranio-nasopharyngeal fistula (risk of entry of air or other material into the cranial cavity)
- Acute sinusitis, otitis media, or perforated ear drum
- Acute or unstable cardiac failure
- Nocturnal or resting angina (risk of infarction or arrhythmias)
- Unstable arrhythmias
- Severely obtunded or heavily sedated patients
- At risk for aspiration of gastric contents
- Impaired ability to clear secretions

If patients are dehydrated or volume depleted, or have persistent atrial fibrillation, their cardiac filling pressures may be low. In these cases, as with any CPAP or ventilatory support, use of the device may lead to a dangerous reduction in cardiac output. The device should not be used in patients who are dehydrated or volume depleted, and should be used with extreme care in patients with atrial fibrillation.

NOTE: When assessing the relative risks and benefits, the health care professional should understand that the device can be set to deliver pressures up to 30 cm H_2O. Also, in the unlikely event of certain fault conditions, a maximum static pressure of 40 cm H_2O is possible.

2.5 Patient Precautions

- The following are potential side effects of noninvasive positive pressure therapy:
  - Ear or sinus discomfort
  - Conjunctivitis
  - Skin abrasions due to noninvasive interfaces
  - Gastric distention (aerophagia)
  - Drying of nose, mouth or throat
  - Eye irritation
  - Skin rashes
  - Chest discomfort

Chapter 3: Introduction

3.1 Overview

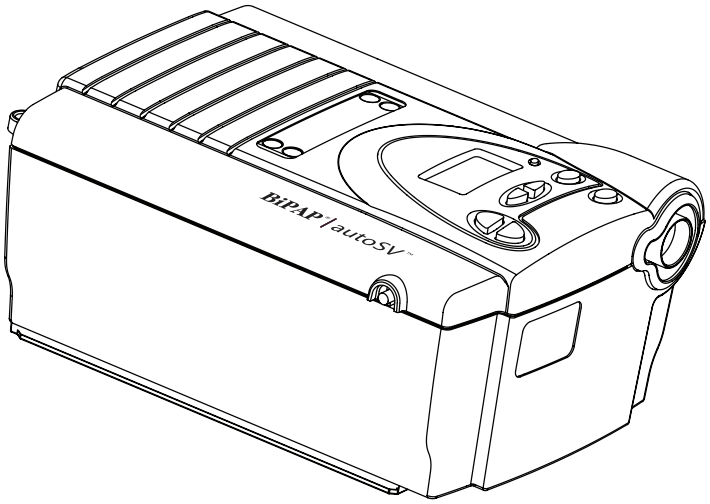


Figure 3-1 The BiPAP autoSV Device

The device, shown in Figure 3-1, is a low-pressure, electrically driven ventilator system with electronic pressure control. The device's pressure controls are adjusted to deliver pressure support for patient ventilatory assistance.

The device is intended to augment patient breathing by supplying pressurized air through a patient circuit. It senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inhalation and exhalation. This assistance is provided by the administration of two levels of positive pressure. During exhalation, pressure is variably positive or near ambient. During inspiration, pressure is variably positive and always equal to or higher than the expiratory level.

The device responds reliably to patient flow rates that indicate movement to inhalation or exhalation, even in the presence of most normal leaks in the patient circuit. Automatic adjustment of this trigger threshold in the presence of leaks makes the system ideal for mask-applied ventilation assistance. The patient-controllable Rise Time feature may enhance patient-ventilator synchrony and patient comfort.

3.2 Operation

This section provides information on the following BiPAP autoSV features:

- Pressure Controls
- Back-up Breath Rate Controls
- Ramp
- Digital Auto-Trak™ Sensitivity

3.2.1 Pressure Controls

The device contains the following controls which are used to configure positive pressure therapies:

- EPAP – The pressure maintained during expiration.
- IPAP Min – The minimum pressure the device can deliver during inspiration.
- IPAP Max – The maximum pressure the device can deliver during inspiration.

With these controls, the device offers the following therapies:

Control Settings	Description
EPAP = IPAP Min < IPAP Max	The device provides CPAP as a base therapy. The device may automatically provide pressure support with inspiratory pressures between IPAP Min and IPAP Max to normalize patient ventilation during sleep disordered breathing events. Refer to Figure 3-2. **Note**: When EPAP = IPAPMin = IPAP Max, this is equivalent to traditional CPAP therapy.
EPAP < IPAP Min < IPAP Max	The device delivers minimum pressure support determined by the EPAP and IPAP Min controls. The device may automatically provide additional pressure support with inspiratory pressures between IPAP Min and IPAP Max to normalize patient ventilation during sleep disordered breathing events. Figure 3-3 illustrates the automatic adjustment of IPAP during a sleep disorder breathing event and during normal breathing. **Note**: When EPAP < IPAP Min = IPAP Max, this is equivalent to traditional bi-level therapy.

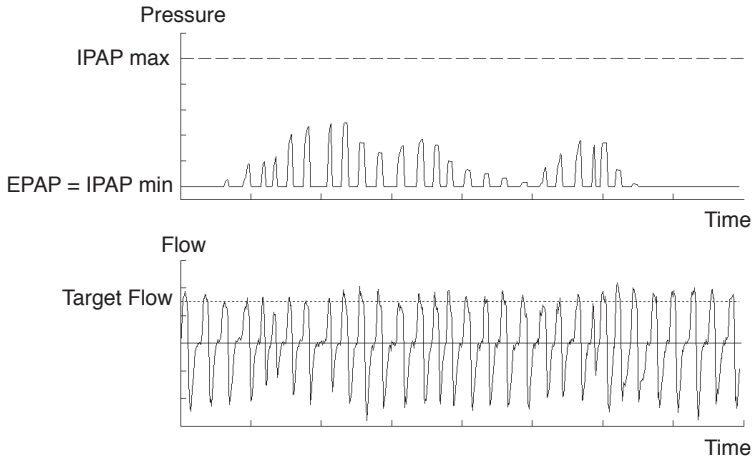


Figure 3-2 CPAP Therapy with Automatic Pressure Support

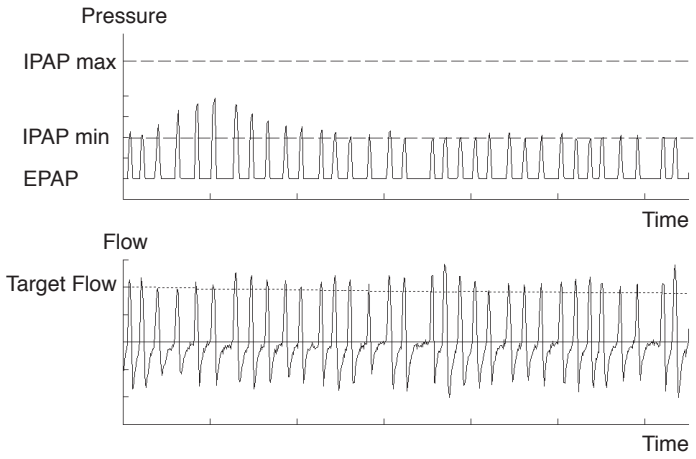


Figure 3-3 Bi-Level Therapy with Automatic Pressure Support

3.2.2 Back-up Breath Rate Controls

In addition to the pressure controls, the device may be configured to deliver machine-triggered breaths if the patient does not spontaneously breathe at a determined rate. Back-up breaths are machine-triggered, machine-cycled breaths. The Rate and Time Insp controls are used to configure back-up breaths to one of three selections.

Control Settings	Description
Back-up Rate: OFF	No back-up breaths are delivered to the patient. The initiation of each breath is exclusively controlled by the patient. The device triggers to IPAP in response to spontaneous inspiratory effort, and cycles to EPAP during exhalation. Figure 3-4 illustrates the trigger and cycle concepts.
Back-up Rate: 4-30 Time Insp: .5 - 3	This selection ensures that the patient will receive a minimum number of breaths per minute if their spontaneous breathing rate drops below the breath rate specified by the Rate control. If the patient fails to initiate an inspiration within the breath period determined by the control, the device triggers a timed breath. The duration of each breath is controlled by the Time Insp control. Figure 3-5 illustrates patient-triggered and machine-triggered breaths when the back-up rate is 4-30.
Back-up Rate: Auto	With Auto selected, the back-up rate and the time of inspiration are automatically determined by the device. Spontaneous breaths are used to compute an average breath period and inspiratory period. (The 2 to 3 breaths prior to central apnea may be insufficient to ventilate. Thus, tidal volumes less than 100 ml are not counted as a breath. Timed breaths are delivered in groups of 5 breaths. The First Timed breath has separate timing criteria as compared to the subsequent 4 breaths.) Figure 3-6 illustrates breathing intervals when the back-up rate is Auto.

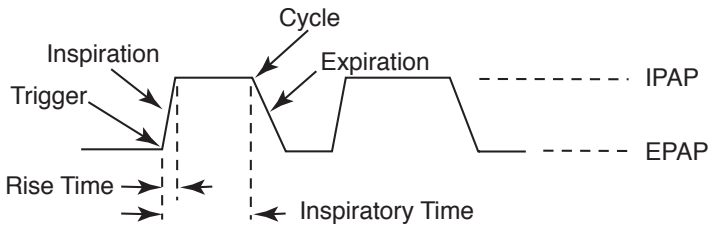
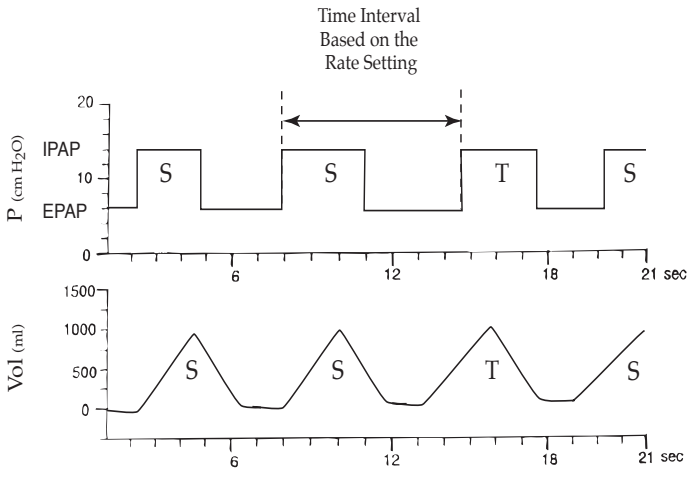


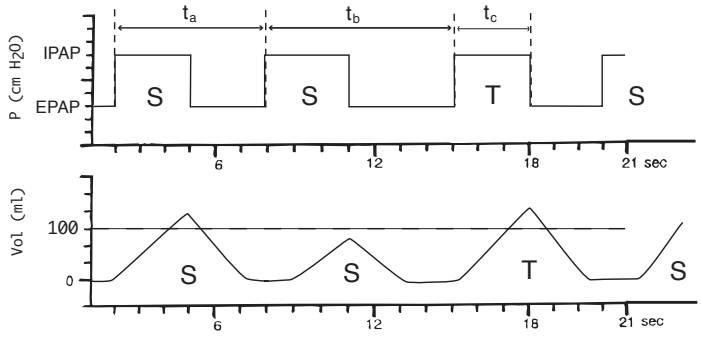
Figure 3-4 Triggering and Cycling when the Back-Up Rate is Off



S = Spontaneously-triggered pressure support breaths (Patient-triggered)
T = Time-triggered, pressure-limited, time-cycled breath (Machine-triggered)

Figure 3-5 Example of Patient-Triggered and Machine-Triggered Breaths when the Back-Up Rate is 4 - 30

t_a = normal breathing interval
t_b = breathing interval that triggers a timed breath
t_c = inspiration time of a timed breath



S = Spontaneously triggered pressure support breaths (Patient-triggered)
T = Time-triggered, pressure-limited, time-cycled breath (Machine-triggered)

Figure 3-6 Breathing Intervals when the Back-Up Rate is Auto

3.2.3 Ramp

The device is equipped with a linear ramp function. When activated, the ramp feature reduces the pressure and then gradually increases (ramps) the pressure to the prescription pressure setting so patients can fall asleep more comfortably. Figure 3–7 illustrates how the ramp function works.

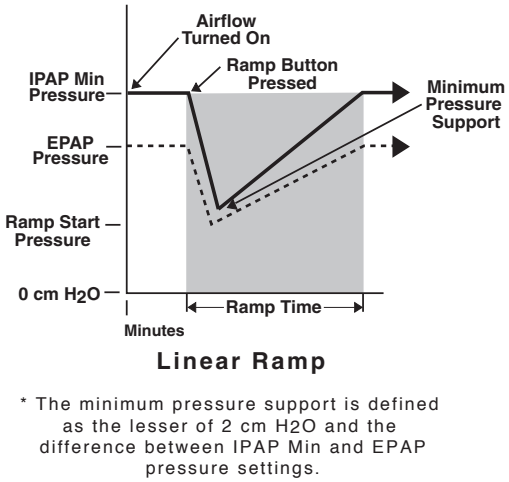


Figure 3-7 The Ramp Function

3.2.4 Digital Auto-Trak™ Sensitivity

An important characteristic of the BiPAP autoSV device is its ability to recognize and compensate for unintentional leaks in the system and to automatically adjust its trigger and cycle algorithms to maintain optimum performance in the presence of leaks. This feature is known as Digital Auto-Trak Sensitivity. The following sections examine this function in detail by describing the leak tolerance function and sensitivity.

3.2.4.1 Leak Tolerance

A microprocessor monitors the total flow of the patient circuit and calculates patient flow values.

A. Leak Estimation: Average and Parabolic

The device uses two leak estimation algorithms. A conservation of mass algorithm is used to compute the average leak for a given pressure support relationship. This average leak is used when large leak variations are present in the system. Average leak is a high estimate during EPAP pressure and a low estimate during IPAP pressure.

A better leak estimate, enabled by the digital system, is the parabolic leak algorithm. Parabolic leak is proportional to the square of the patient pressure; therefore, the leak estimate is correlated to the changing patient pressure. Both algorithms include unintentional circuit leak and are averaged over several breaths.

B. Patient Flow

The total circuit flow is comprised of the circuit leak and the patient flow. The calculated patient flow is the total flow minus the circuit leak. Patient flow is a primary input into the triggering and cycling mechanisms.

3.2.4.2 Sensitivity

An essential feature of the device's triggering function is its ability to effectively sense spontaneous breathing efforts, which causes the ventilator to trigger to IPAP and cycle to EPAP. Because no preset sensitivity threshold can assure patient and machine synchrony with changing breathing efforts and circuit leaks, the device continuously tracks patient breathing patterns and automatically adjusts sensitivity thresholds to ensure optimum sensitivity as breathing patterns change or as circuit leaks change. The algorithm used to ensure optimum sensitivity is the Volume Trigger.

Volume Trigger (EPAP to IPAP)

The volume trigger is the method used to trigger IPAP during spontaneous breathing. The volume trigger threshold is 6 ml of accumulated patient inspiratory volume. When patient effort generates inspiratory flow causing 6 ml of volume, IPAP is triggered.

Shape Trigger (EPAP to IPAP)

The shape trigger is another method used to trigger IPAP during spontaneous breathing. This method continuously tracks patient inspiratory and expiratory flow and adjusts the spontaneous trigger threshold for optimum sensitivity. The shape signal appears as a shadowy image of the patient's actual flow. The shape signal functions as a sensitivity threshold at inspiration. When the patient's flow rate crosses the shape signal, the unit changes pressure levels. Figure 3–8 illustrates how the shape signal is superimposed onto the actual waveform to trigger to IPAP.

The shape signal is created by offsetting the signal from the actual patient flow by 15 LPM and delaying it for a 300 msec period. This intentional delay causes the shape signal to be slightly behind the patient's flow rate. A sudden change in patient flow will cross the shape signal, causing the pressure level to change.

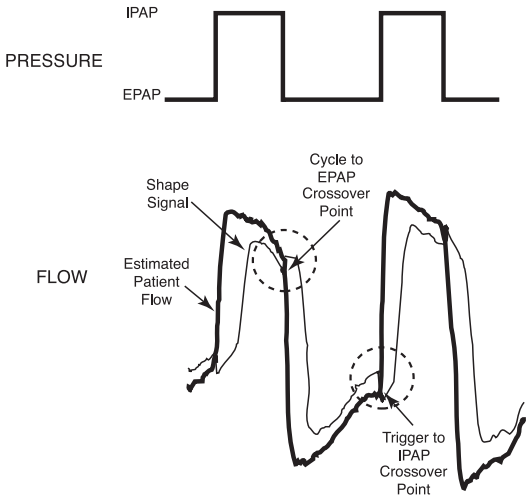


Figure 3-8 Shape Signal

Tracking the patient's flow pattern with the shape signal provides a sensitive mechanism to trigger to IPAP in response to changing breathing patterns and circuit leaks.

Spontaneous Expiratory Threshold (IPAP to EPAP)

The method used to cycle off IPAP during spontaneous breathing is called Spontaneous Expiratory Threshold (SET). The SET rises in proportion to the inspiratory flow rate on each breath. When the SET and the actual patient flow value are equal, the unit cycles to EPAP.

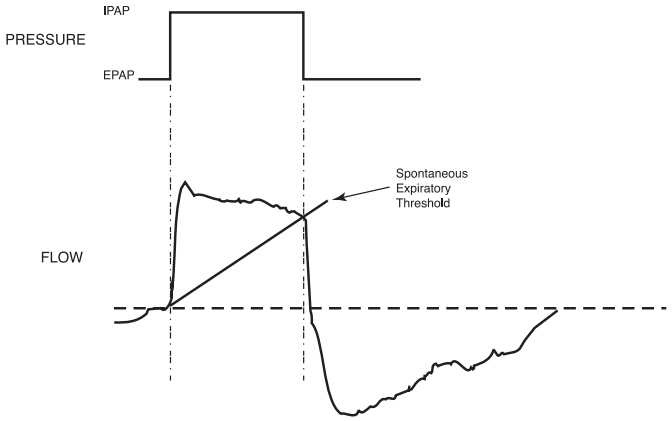


Figure 3-9 Spontaneous Expiratory Threshold

Maximum IPAP Time (IPAP to EPAP)

A maximum IPAP time of 3.0 seconds acts as a safety mechanism to limit the time spent at the IPAP level during spontaneous breathing. Once the time limit is reached, the unit automatically cycles off IPAP to the EPAP level.

Summary

The sensitivity criteria for spontaneous breathing can be summarized as follows:

Spontaneous Trigger to IPAP

A transition from EPAP to IPAP occurs when one of the following conditions is met:

- Patient flow exceeds the shape signal
- 6 ml inspired patient volume

Cycle to EPAP

The transition from IPAP to EPAP occurs when one of the following conditions is met:

- Spontaneous Expiratory Threshold (SET) is achieved
- A 3.0 second maximum IPAP time has occurred (safety feature)

3.3 Access Levels

There are two levels of access:

- Provider Mode
- User Mode

3.3.1 Provider Mode Access Level (Setup)

The Provider mode unlocks additional parameters that are not available to the patient. This mode is accessed by completing the following steps:

1. Plug in the device to power up the device.
2. Press the **Right User** button and the **SILENCE** button simultaneously for at least two seconds (see Figure 3-10). **SETUP** appears in the top right corner of the display, and the EPAP Setting screen will display. This indicates that you are now in Provider mode.

NOTE: It does not matter whether you press the **Right User** button or the **SILENCE** button first.

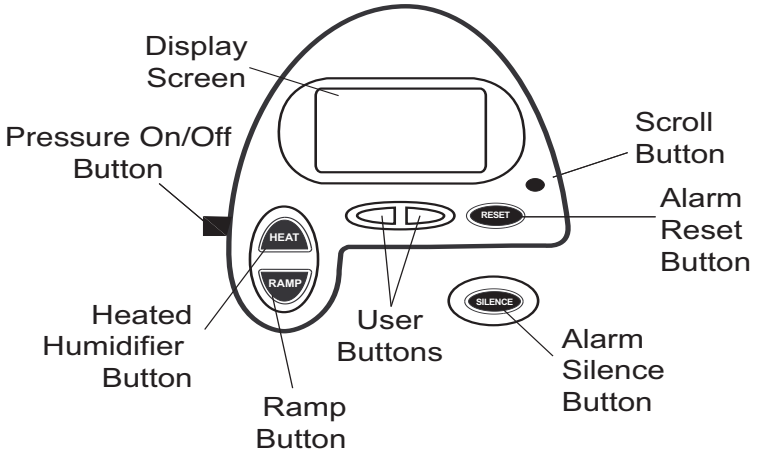


Figure 3-10 Control Panel

NOTE: The device can be configured to remain in Provider mode by changing the Access Level Setting. See Chapter 6 for more information.

3. Navigate the screens and change the settings as described in Chapter 6.

You can display and modify the following settings in Provider mode:

- EPAP pressure
- IPAP minimum pressure
- IPAP maximum pressure
- Breath rate
- Timed inspiration
- Rise time
- Ramp length
- Ramp starting pressure
- Apnea alarm (enable/disable)
- Patient disconnect alarm (enable/disable)
- Low minute ventilation alarm (enable/disable)
- Therapy hours (erase or save)
- LED Backlight
- Access Level Setting

3.3.2 User Mode Access Level

To switch the device from Provider mode to User mode, change the Access Level Parameter from **1** to **0** in the Access Level Setting screen. See Chapter 6 for more information.

NOTE: If you temporarily set the device to Provider mode by pressing the **Right User** button and the **SILENCE** button, the device will return to User mode when any of the following occurs:

- The **SILENCE** button is pressed.
- Any parameter screen times out.
- You press the **Left User** button while the EPAP Setting screen is displayed.
- You press the **Right User** button while the Access Level Setting screen is displayed.

The following settings can be modified in User mode:

- Rise time setting
- Ramp start pressure setting (if enabled)
- LED backlight for control buttons (enable/disable)
- Humidifier heat setting (from the Humidifier Setting screen)

The following is also true in User mode:

- The Rise Time Setting screen is only displayed if the IPAP Max is greater than EPAP.
- The Ramp Start Pressure Setting screen is only displayed if the Ramp Length setting is greater than zero.

3.4 Definitions, Acronyms, and Abbreviations

The following terms appear in this manual:

- APS—Automatic Pressure Support
- BiPAP—Bi-level Positive Airway Pressure
- BPM—Breaths Per Minute
- CSA—Central Sleep Apnea
- CPAP—Continuous Positive Airway Pressure
- Cycle—The transition from inspiration to expiration.
- EPAP—Expiratory Positive Airway Pressure
- High Priority Alarm—Alarm signal indicating a condition that requires immediate attention
- IPAP—Inspiratory Positive Airway Pressure
- IPAP Max—The maximum IPAP setting established by the health care professional.
- IPAP Min—The minimum IPAP setting established by the health care professional.
- LCD—Liquid Crystal Display
- LEAK—Measured Average Leak
- LED—Light Emitting Diode
- Low Minute Ventilation—A condition in which the patient is not receiving a specified volume of air on a per minute basis.
- Low Priority Alarm—Signal indicating an information message.
- LPM—Liters Per Minute
- Medium Priority Alarm—Alarm signal indicating a condition that requires operator awareness.
- MinVent—Minute Ventilation
- NPPV—Non-invasive Positive Pressure Ventilation
- Operate State—The state of the BiPAP autoSV device when the device and the airflow are both on.
- OSA—Obstructive Sleep Apnea
- Ramp—A feature that may increase patient comfort when therapy is started. The ramp feature will reduce the pressure and then gradually increase (ramp) the pressure to the prescription pressure setting so patients can fall asleep more comfortably.
- RR—Respiratory Rate
- SET—Spontaneous Expiratory Threshold
- Standby State—The state of the BiPAP autoSV device when it is on, but the airflow is off.
- T_i—Inspiratory Time
- Trigger—The transition from expiration to inspiration.
- V_{TE}—Exhaled Tidal Volume

3.5 Symbol Key

The following symbols appear on the device label:

Symbol	Meaning
	**Attention, consult accompanying documents**
	**DC Power**
	**Pressure On/Off**
	**Type BF Applied Part**
	**Class II (Double Insulated)**
	**European CE Declaration of Conformity**
	**Canadian/US Certification**
	**Electrostatic Discharge**
IPX1	**Drip Proof Equipment**
	**UL Recognized for Canada and the United States**
	**TUV Safety Standard Compliance**
	**No User Serviceable Parts**

3.6 Service

If you need product support, call the Respironics Customer Service department at 1-724-387-4000 or 1-800-345-6443. You can also use the following address:

Respironics
1001 Murry Ridge Lane
Murrysville, PA 15668

Visit the Respironics web site at: www.respironics.com.

Chapter 4: Controls and Displays

This chapter describes the control panel and displays, the patient circuit connections, and the rear panel connections.

4.1 Controls and Displays

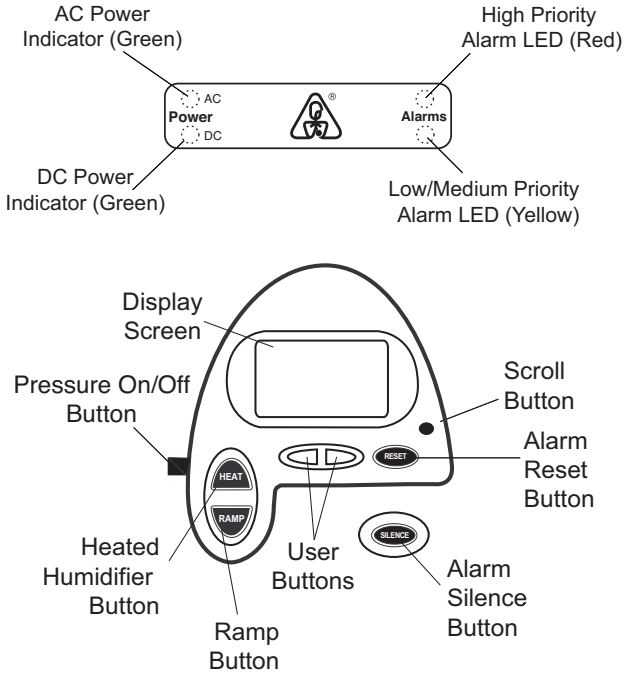


Figure 4-1 The Control Panel

Figure 4-1 illustrates the control panel. The control panel includes:

- A display screen where all device settings appear
- Control buttons
- Alarm indicators
- Power indicators

4.1.1 Display Screen

The display screen shows operating parameters, instructions, and messages. A backlight activates when the user buttons are pressed, and remains on until there are no buttons pressed for one minute. Figure 4-2 shows the display screen.

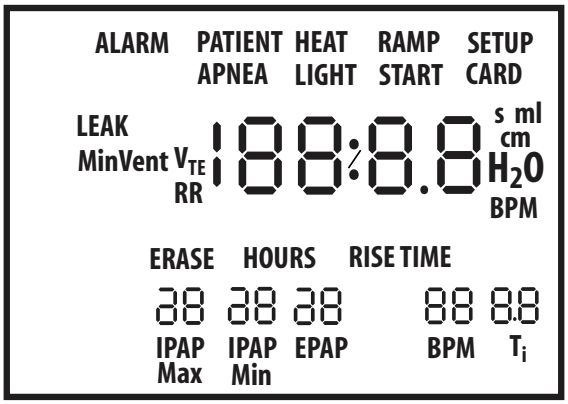


Figure 4–2 Display Screen

The information shown on the display screen is defined as follows:

ALARM	Indicates that the device requires user attention as indicated on the screen.
APNEA	Indicates that an apnea alarm has occurred.
BPM	Indicates that a breath rate setting is being displayed. This symbol flashes when the device is providing timed backup breaths.
CARD	Indicates that a SmartCard is inserted and detected.
cm H_2O	Indicates that the alphanumeric digits are displaying a pressure value.
EPAP	Indicates that an EPAP pressure setting is being displayed.
ERASE	Indicates that the user may clear the Therapy Hour Meter.
HEAT	Indicates that the humidifier is turned on and/or its setting is displayed.
HOURS	Indicates that the Therapy Hour Meter is being displayed.
IPAP Max	Indicates that an IPAP *maximum* pressure setting is being displayed.
IPAP Min	Indicates that an IPAP *minimum* pressure setting is being displayed.
LEAK	Indicates that the Estimated Leak Rate is being displayed.
LIGHT	Indicates that the control pad LED backlight setting is being displayed or is active.
LPM	Indicates that the value displayed is in liters per minute.
MinVent	Indicates that the Estimated Minute Ventilation is being displayed.
ml	Indicates that the value displayed is in milliliters.
PATIENT	Indicates that a Patient Disconnect alarm is active or a patient disconnect alarm setting is being displayed.
RAMP	Indicates that the Ramp function is in progress or the ramp length setting is being displayed.
RAMP START	Indicates that the Ramp Starting Pressure is being displayed.
RISE TIME	Indicates that a rise time setting is being displayed.
RR	Indicates that the Respiratory Rate (RR) is being displayed.
s	The small "s" on the right side of the display (above "cm H_2O") indicates that the alphanumeric digits are displaying a time value, in seconds.
SETUP	Indicates that the device is in Provider mode and not in User mode.
T_i	Indicates that an inspiratory time setting is being displayed.
V_{TE}	Indicates that the Estimated Exhaled Tidal Volume is being displayed.

4.1.2 Control Buttons

The control buttons, shown in Figure 4-3, are defined below.

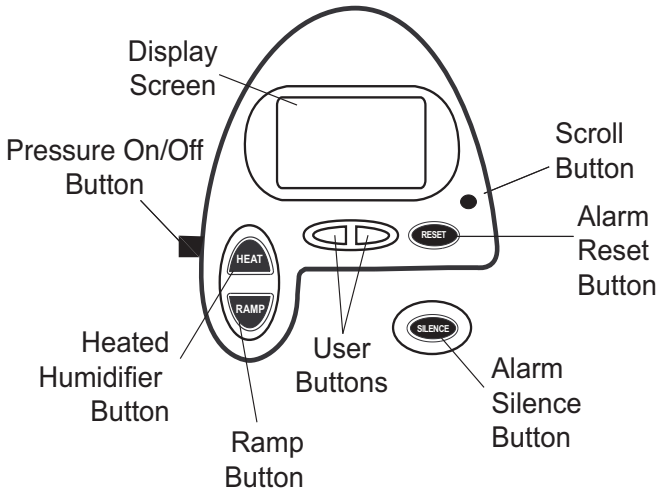


Figure 4–3 Control Buttons

This button starts or stops the device's airflow. Press the button in to turn the airflow **On**. This puts the device in the Operate state. When the button is in the **Off** position, the device is in the Standby state, any ramp in progress is terminated, the alarms are reset (except for the System Errors alarm), and the humidifier is turned off. The **Pressure On/Off** button is independent of the display screen. Figure 4–4 shows the button's On and Off positions.

Figure 4–4 Pressure On/Off Button (on the side of the device)

HEAT When the optional REMstar Heated Humidifier has been prescribed, this button controls the humidifier's output. Follow the instructions included with the humidifier. This button can also be used to adjust the parameters shown in the provider and user menu screens.

RAMP When the airflow is turned on, this button lowers the airflow pressure, allowing the patient to fall asleep more easily. This button can also be used to adjust the parameters shown in the provider and user menu screens.

Press the left and right user buttons to navigate the display screens.

SILENCE This button temporarily silences the audible portion of an alarm. Additionally, it allows you to exit a parameter screen.

RESET This button acknowledges an alarm and resets the device for alarm detection.

Use this button to scroll through the measured monitoring parameters.

4.1.3 Indicators

The alarm and power indicators, shown in Figure 4–5, are described below.

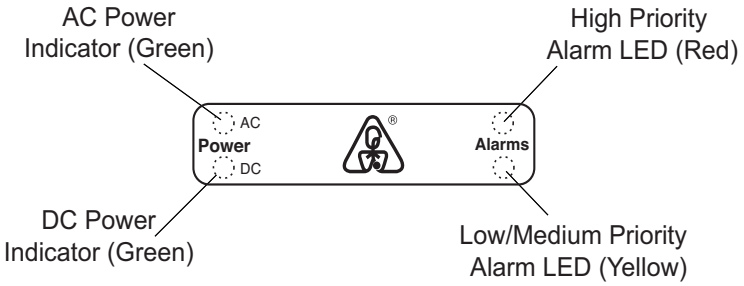


Figure 4–5 Alarm and Power Indicators

AC Power Indicator	The green **AC Power** LED illuminates when the device is connected to AC power.
DC Power Indicator	The green **DC Power** LED illuminates when the device is connected to DC power.
High Priority Alarm Indicator	The red **High Priority Alarm** LED illuminates when a high priority patient or system alarm occurs.
Low/Medium Priority Alarm Indicator	The yellow **Low/Medium Priority Alarm** LED illuminates when a medium or low priority patient or system alarm occurs.

NOTE: All LED indicators temporarily turn on when the device is first plugged in.

4.1.4 Audible Alarms and Indicators

Audible alarms and indicators, discussed in detail in Chapter 7, can be heard in the following situations:

- **Power Failure** – An alarm sounds when power is lost.
- **High priority system or patient alarms** – An alarm sounds several times at intervals for a high priority alarm.
- **Medium priority system alarms** – An alarm sounds three times for a medium priority alarm.
- **Low priority system alarms** – An alarm sounds twice for a low priority alarm.
- **Provider mode** – An alarm sounds twice when the provider mode is accessed using the key sequence described in Section 3.3.1.
- **SmartCard activity** – An alarm sounds once when the SmartCard is inserted or removed.
- **Power on** – An alarm sounds once when the device's power cord is connected.
- **Confirmation** – An alarm sounds once when the airflow is turned on, when the humidifier parameter screen is entered, and when the humidifier is turned on.

4.2 Navigating the Screens

Note the following when navigating the Provider or User mode screens:

- The **Left** and **Right User** buttons allow you to go to the previous setting or the next setting, respectively.
- The **HEAT** and **RAMP** buttons operate as up and down buttons to adjust the settings. Pressing and holding the **HEAT** or **RAMP** buttons down for at least 2 seconds will change the settings at a faster rate.
- The **SILENCE** button allows you to exit a Provider or User mode screen.
- The small circular Scroll button (◉) (located next to the **RESET** button) allows you to view measured parameters from the Monitoring screen. See Chapter 6 for more information.
- The alphanumeric digits and symbols flash to indicate setting adjustment.

4.2.1 LED Backlight for Buttons

The **SILENCE**, **RESET**, **RAMP**, and **HEAT** buttons can be lit by an LED backlight. The LED backlight is on when the device is in the Standby state or when the System Self Test Screen is displayed. When the device is in the Operate state, the LED backlight is lit according to the setting in the LED backlight screen. The LED backlight may flash to indicate an alarm condition as described in Chapter 7.

Control Panel Inactivity

Some screens have timeout periods. The screen's timer starts when the screen is initially displayed, and is restarted whenever a button is pressed. When a screen times out, the LCD backlight is turned off and the Monitoring/Standby screen is displayed. The LCD backlight turns back on when a button is pressed again.

4.3 Patient Circuit Connection

The patient circuit is connected to the breathing circuit connection shown in Figure 4–6. The breathing circuit connection accepts a bacteria filter or a tubing connector for reusable or disposable tubing.

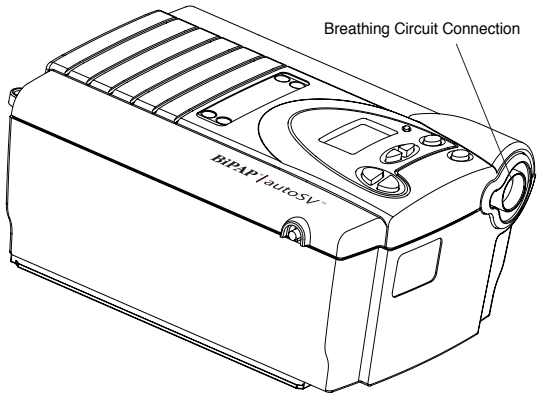


Figure 4–6 Breathing Circuit Connection

4.4 Rear Panel

Figure 4–7 shows the rear panel.

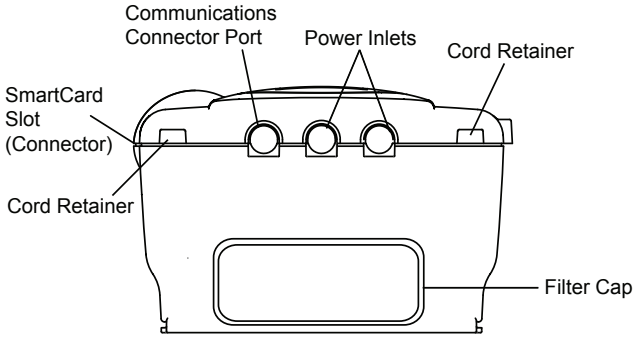


Figure 4–7 Rear Panel

NOTE: The SmartCard connector (SmartCard slot) is located on the side of the device.

WARNING: In order to ensure proper protection against electric shock, only communications accessories with an IEC 60601-1 approved power supply may be connected through the SleepLink interface. All IEC 950 devices must only be connected to the 7-pin connector with the Respironics Isolation cable (Part Number 1012865).

The rear panel contains the following:

- A communications connector that accepts the Respironics Communications Cable for computer and external communications or a remote alarm, when available. (Use only with an IEC 60950 approved computer.)
- Two power inlets: one for connecting the external AC power supply and another for connecting the DC power adapter.
- The filter cap that is removed to inspect the inlet air filters.
- Two cord retainers that provide strain relief for the power cord.

4.5 SmartCard

The device is delivered with the SmartCard installed. The SmartCard records the following data:

- Date
- Time
- Leak
- Pressure
- Tidal volume
- Peak flow
- Apnea events
- Hypopnea events
- Duration of each use (minimum storage capacity is six months)

When capacity is reached, the oldest data is overwritten. Using the Respironics SmartCard reader/writer and the Encore Pro software, you can download and view the usage data. Follow the instructions included with the Encore Pro software to download the data.

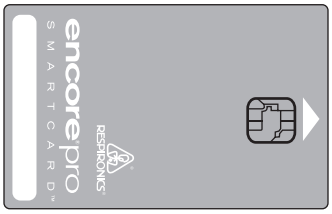


Figure 4–8 Encore Pro SmartCard

NOTE: If the card is not installed, the device usage will not be recorded. When a SmartCard is installed, **CARD** appears in the upper right corner of the display screen.

Chapter 5: Setup

5.1 Preparing the Device

This section contains information on:

- Installing the air filters.
- Assembling the patient circuit.
- Supplying power to the device.
- Startup.

5.1.1 Installing the Air Filters

The device uses one or two removable filters at the air inlet. The disposable white ultra-fine filter is optional. You must install the gray foam filter before operating the device. The foam filter is washable and reusable. For cleaning instructions, see Chapter 8.

CAUTION: A properly installed, undamaged foam filter is required for proper operation.

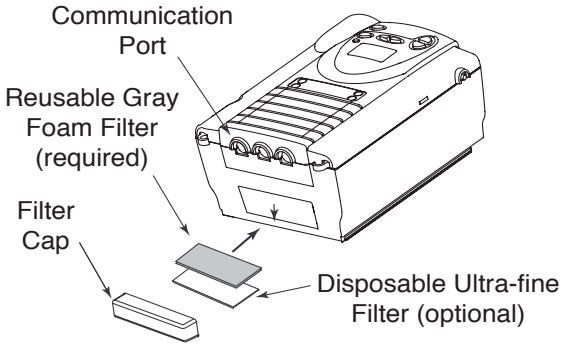


Figure 5-1 Installing the Air Filters

To install the air filters, complete the following steps:

1. If you are using the optional white ultra-fine filter, place it against the gray foam filter so the soft side of the ultra-fine filter touches the gray foam filter. When the filters are installed, the hard plastic side of the white filter will touch the inside of the device.
2. Slide the filters into the air inlet at the rear of the device (with the white filter going in first, if it's used). Push them down into the recess as shown in Figure 5-1.
3. Position the cap so that the small opening on the cap is facing down.
4. Snap the cap into place.

See Chapter 8 for information about cleaning or replacing the filters.

NOTE: The filter cap should be installed with the air inlet opening at the bottom.

5.1.2 Assembling the Patient Circuit

WARNING: The exhalation device (e.g., the Whisper Swivel® II) or exhalation port (on masks with an integrated exhalation port) is designed to exhaust CO_2 from the patient circuit. Do not block or seal the ports on the exhalation device.

1. Assemble the patient circuit according to the configurations presented in Chapter 10.
2. If required, connect a bacteria filter to the breathing circuit connection (shown in Figure 5-2), and connect the patient tubing to the outlet of the bacteria filter.
   - If the bacteria filter is not required, connect the patient tubing directly to the breathing circuit connection.
   - If a humidifier is to be used, connect the inlet to the bacteria filter outlet or to the breathing circuit connection.

A completed assembly (without humidifier) appears in Figure 5-2.

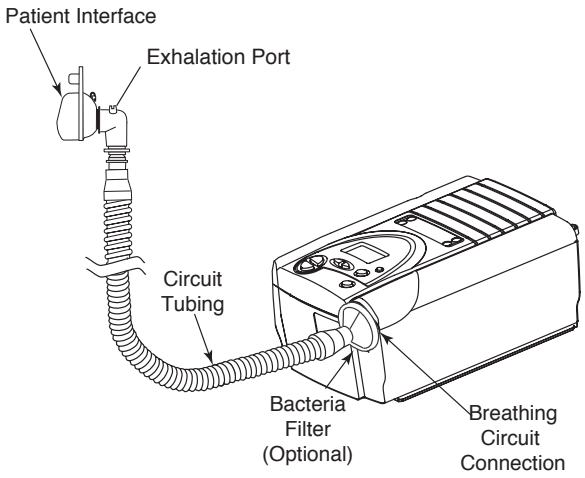


Figure 5-2 An Example of a Typical Circuit

5.1.3 Supplying Power to the Device

WARNING: The BiPAP autoSV device can operate on AC or DC power. The DC power option is not intended as a battery backup during use of AC power.

CAUTION: When DC power is obtained from a vehicle battery, the device should not be used while the vehicle's engine is running. Damage to the device or the vehicle may occur.

WARNING: Route the wires to avoid tripping.

5.1.3.1 AC Operation

WARNING: For proper use, the external AC power supply **must** be placed feet down, in the upright position, as shown in Figure 5–3.

1. Plug the pronged end of the AC power supply's cord into an electrical outlet that is not controlled by a wall switch.
2. The external AC power supply features a cord retainer to provide strain relief for the AC power cord. Wrap the cord around the AC power supply's cord retainer, using the wire tie supplied with your power supply.
3. Leaving a small amount of slack in the cord, connect the cord on the other side of the power supply to one of the power inlets on the device. The power cord has a locking connector. To properly plug the cord in:
   a. Pull the locking mechanism back.
   b. Push the connector into place.
   c. Release the lock.
4. Wrap the cord around the device's power cord retainer, which provides strain relief for the power cord.
5. Ensure that all connections are secure.

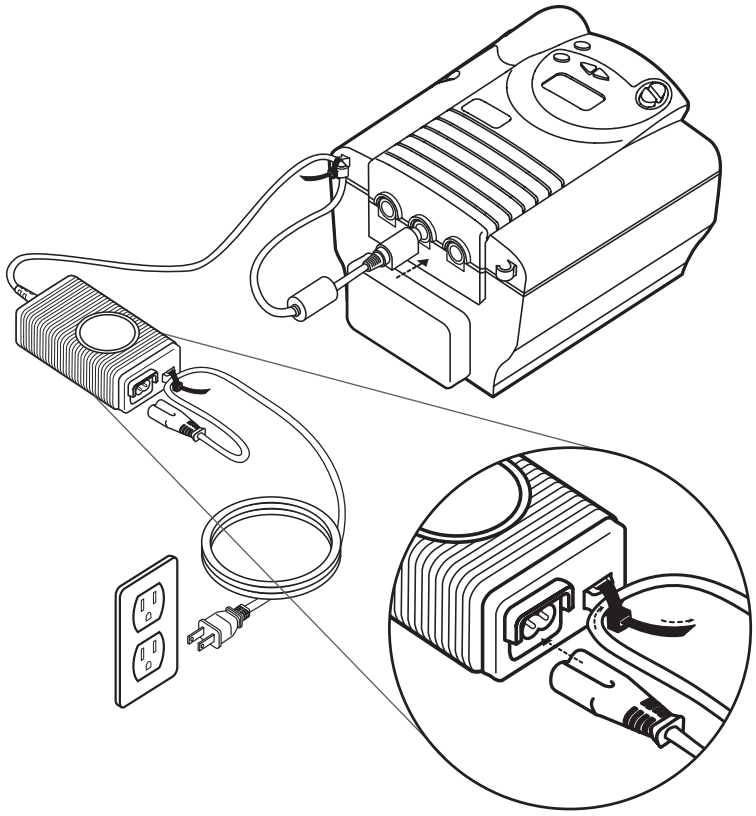


Figure 5-3 Using the External Power Supply

NOTE: You can plug the cord into either of the power inlets on the back of the device.

NOTE: If you need to disconnect the power cord from the device, slide the locking connector back and then remove the power cord.

5.1.3.2 DC Operation

You can operate the device on DC power by using the Respironics DC power adapter accessory. See the DC power adapter instructions for information on how to operate the device using DC power.

CAUTION: When DC power is obtained from a vehicle battery, the device should not be used while the vehicle's engine is running. Damage to the vehicle may occur.

CAUTION: Only use the Respironics DC power adapter available from your health care professional. Use of any other system may cause damage to the device or the vehicle.

5.1.4 Startup

When the power cord is plugged into an AC or DC power source, the device sounds a confirmation alarm, and the control panel buttons light up.

NOTE: If the alarm does not sound or the buttons do not light up, the device requires servicing. Additionally, if any of the alphanumeric digits shown in Figure 5–4 do not display on the Self Test screen, the device requires servicing.

1. The first screen to appear is the Self Test screen:

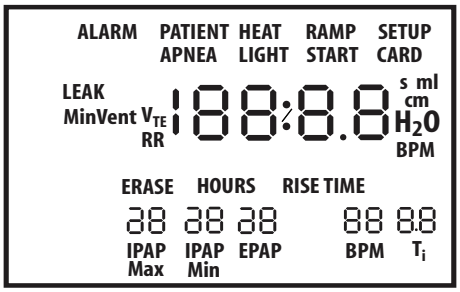


Figure 5-4 Self Test Screen

2. The next screen displays the software version:

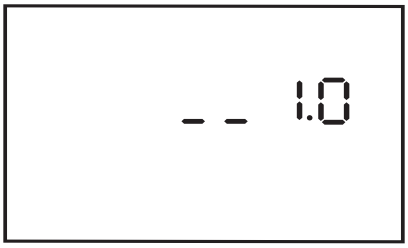


Figure 5-5 Software Version Screen

NOTE: The version number shown in Figure 5-5 is an example, your device may have a different software version installed.

3. The Blower Hours Screen then appears, which displays the Blower Hours Time Meter:

Figure 5-6 Blower Hours Screen

NOTE: With the exception of the ⏻ button, buttons on the control panel are inactive during these first three screens.

NOTE: Each of the first three screens appears for approximately 1-3 seconds.

4. The next screen to appear is the Standby screen:

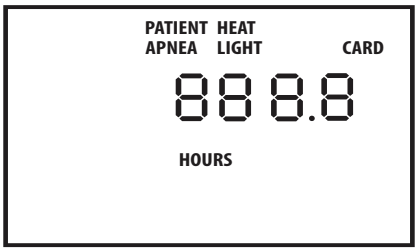


Figure 5-7 Standby Screen

The Standby screen appears when the device is in the Standby state. Pressing the ⏻ button in puts the device in the Operate state. The Monitoring screen then appears:

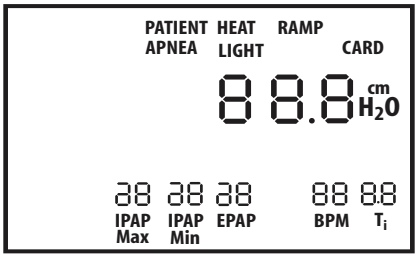


Figure 5-8 Monitoring Screen

Both the Monitoring and the Standby screens display **PATIENT**, **APNEA**, **LIGHT**, and **HEAT** if these features are enabled. Likewise, **CARD** displays if a SmartCard is inserted, and **SETUP** displays if the access level is set to Provider mode. The Monitoring screen displays **RAMP**, if ramp is enabled and the **RAMP** button has been pressed. If fixed timed backup rate is prescribed, **BPM** and $\mathbf{T_i}$ will be displayed if the health care professional set the breath rate between 4-30 BPM. For more information about the Monitoring Screen and parameters that you can view from here, see Chapter 6.

5. When in the Standby or Monitoring screens, you can modify the Humidifier setting by pressing and holding the **HEAT** button until the screen below appears (Figure 5–9).

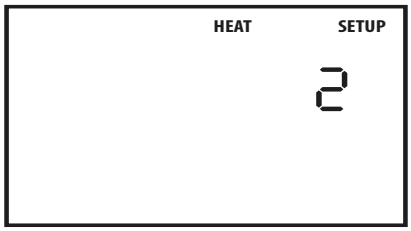


Figure 5–9 Humidifier Setting Screen

You can increase or decrease the humidifier setting from 1 to 5 in increments of 1. The setting changes immediately as you adjust it.

5.1.5 Entering Provider Mode

There are two ways to select Provider mode access.

1. To temporarily enter Provider mode when the device is in User mode, hold down the **Right User** button and **SILENCE** button simultaneously for at least 2 seconds. **SETUP** appears in the upper right corner of the screen, and the EPAP setting screen displays.
2. Once the device is in Provider mode, you can configure the device to remain in Provider mode via the Access Level screen, as described in Section 6.1.2.

IMPORTANT: Prescribed therapy settings can only be set in Provider mode. To prevent patients from tampering with the settings, do not allow them to access Provider mode.

5.1.6 Performance Verification

After powering up the device and entering Provider mode, perform the operational verification as described in Chapter 11.

5.2 Setting up the Device

Before using the device on a patient, set the prescription:

1. To change the settings, see Chapter 6.
2. To set the necessary alarms, see Chapter 7.
3. Verify that the device is not left in Provider mode.

5.3 Connecting the Patient

NOTE: Before connecting the patient to the device, check the integrity of the patient circuit, exhalation port, and alarms.

1. Make sure the device is in User mode. (See Chapter 6.)
2. Turn the device's airflow on by pressing in the ⏻ button.
3. If oxygen is being used, turn on the oxygen flow. Make sure you place the Respironics Pressure Valve (Part Number 302418) in-line with the patient circuit.

WARNING: Always turn the airflow on before turning on the oxygen, and always turn the oxygen off before turning off the airflow.

4. Place the mask on the patient.

5.4 Setting up the SmartCard

5.4.1 Downloading Data

You can download data from the SmartCard by following the steps below:

1. Connect a Respironics SmartCard reader/writer directly to an IEC60950 Windows-compatible computer following the instructions included with the reader/writer. Remove the SmartCard from the device and insert it into the reader/writer.
2. Follow the instructions included with your Encore Pro software to download the data.

WARNING: Any IEC 60950 device must be connected through the 7-pin mini-din connector with a Respironics-supplied isolation cable (Part Number 1012865).

5.4.2 Programming a SmartCard

1. Connect a Respironics SmartCard reader/writer directly to an IEC60950 Windows-compatible computer following the instructions included with the reader/writer. Remove the SmartCard from the device and insert it into the reader/writer.
2. Follow the instructions included with your Encore Pro software to program the SmartCard.
3. Remove the SmartCard from the reader/writer. If desired, write the patient's name on the front of the card.

5.4.3 Changing Settings Using a SmartCard

To change the settings in the device using a programmed SmartCard:

1. Make sure the device is plugged in. Insert the programmed SmartCard into the slot on the right side of the device (symbol side facing up). When the Monitoring or Standby screen displays **CARD**, this indicates that the card is inserted correctly.
2. Turn the airflow on to verify the new prescription setting. The card can now be removed or you can leave the card in the device to record device usage. Once the prescription settings have been transferred to the device, they will be deleted from the SmartCard.

Chapter 6: Changing Settings

This chapter describes the settings that can be changed when the BiPAP autoSV device is in the Provider and User modes.

6.1 Changing Settings in Provider Mode

Accessing the Provider mode setup level unlocks additional settings that cannot be changed while in User mode. When in Provider mode, **SETUP** appears in the top right corner of the display. To temporarily access the Provider mode while the device is in User mode, simultaneously press the **Right User** button and the **SILENCE** button, and hold for at least 2 seconds.

NOTE: It does not matter whether you press the **Right User** button or the **SILENCE** button first.

An audible indicator sounds when you have successfully accessed the Provider mode. To exit Provider Mode, press the **SILENCE** button.

6.1.1 Navigating Screens in Provider Mode

Figure 6–1 shows how to navigate the Provider mode screens using the **Left** and **Right User** keys. The parameter symbol and setting will flash.

NOTE: When changing any setting in the Provider mode (except for the EPAP, IPAP Min, IPAP Max, and Ramp Start Pressure settings), once a maximum setting is reached, it will roll over back to the minimum setting, and likewise, once a minimum setting is reached, it will roll over back to the maximum setting for that parameter.

For example, the minimum Humidifier setting is 1 and the maximum is 5. Once the Humidifier setting is increased to 5, if increased again, it will roll over to 1. Or, once the Humidifier setting is decreased to 1, if decreased again, it will roll over to 5.

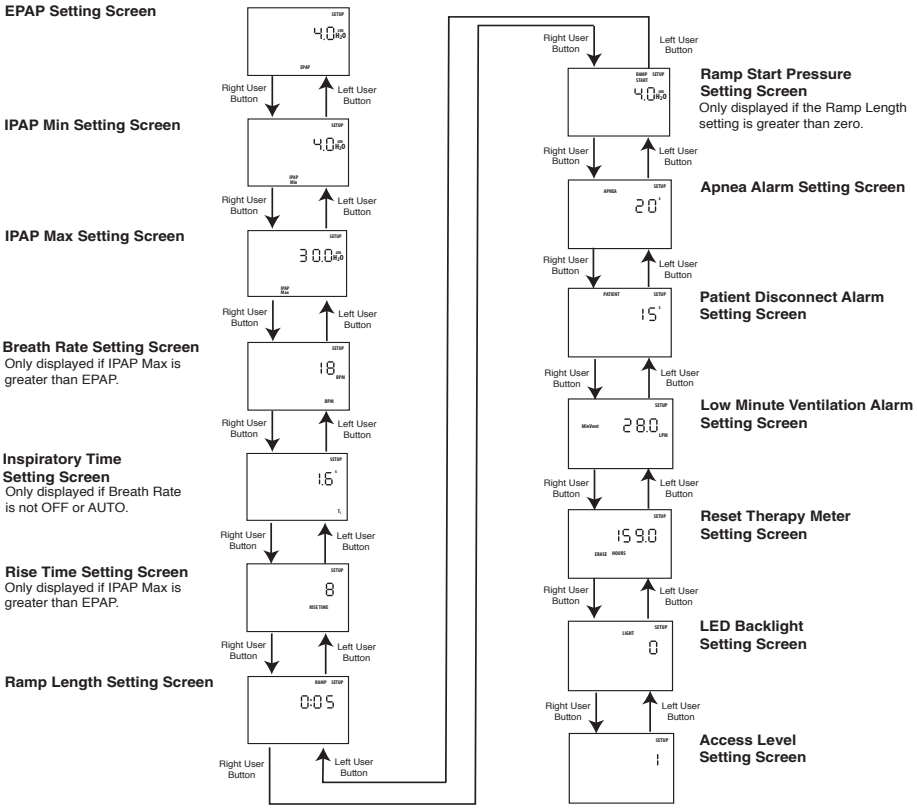


Figure 6–1 Navigating the Provider Mode Screens

6.1.2 Changing Settings in Provider Mode

From each of these screens, press the **Right User** button to access the next one. Likewise, press the **Left User** button to access the previous screen.

1. EPAP Setting Screen

The EPAP Setting screen is shown in Figure 6–2.

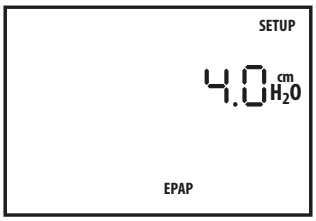


Figure 6–2 EPAP Setting Screen

Increase or decrease the EPAP pressure by pressing the **HEAT** and **RAMP** buttons until the correct pressure appears. You can adjust the pressure from 4 to 25 cm H_2O in 1 cm H_2O increments.

WARNING: High EPAP pressures can cause the patient discomfort. Carefully evaluate the patient if you set the EPAP level above 15 cm H_2O.

NOTE: If the EPAP is set to less than the ramp start pressure, the ramp start pressure automatically sets to the EPAP.

NOTE: If EPAP is greater than IPAP Min, then IPAP Min automatically sets to EPAP.

2. IPAP Min Setting Screen

The IPAP Minimum Setting screen is shown in Figure 6–3.

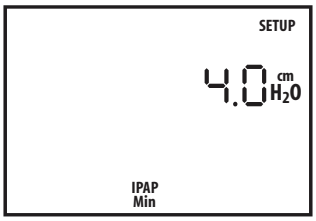


Figure 6–3 IPAP Minimum Setting Screen

Increase or decrease the IPAP minimum pressure setting by pressing the **HEAT** and **RAMP** buttons until the correct pressure appears. You can adjust the IPAP minimum setting from 4.0 cm to 30.0 cm in 1 cm H_2O increments.

NOTE: The IPAP Min value must be equal to or greater than the EPAP value.

NOTE: If the IPAP Min Setting is set greater than IPAP Max setting, the IPAP Max automatically sets to IPAP Min.

3. IPAP Max Setting Screen

The IPAP Maximum Setting screen is shown in Figure 6–4.

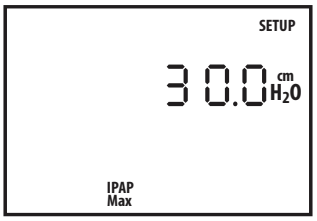


Figure 6–4 IPAP Maximum Setting Screen

Increase or decrease the IPAP maximum pressure setting by pressing the **HEAT** and **RAMP** buttons until the correct pressure appears. You can adjust the IPAP maximum setting from 4.0 cm to 30.0 cm in 1 cm H_2O increments.

NOTE: The IPAP Max value must be equal to or greater than the IPAP Min value.

4. Breath Rate Setting Screen

The Breath Rate Setting screen is shown in Figure 6–5.

NOTE: The Breath Rate Setting screen displays only if IPAP Max is greater than EPAP.

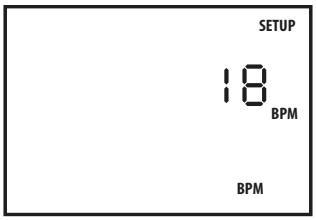


Figure 6–5 Breath Rate Setting Screen

Increase or decrease the breath rate by pressing the **HEAT** and **RAMP** buttons until the correct setting appears. You can adjust the breath rate from 0 to 30 in 1 BPM increments.

5. Inspiratory Time Setting Screen

The Inspiratory Time Setting screen is shown in Figure 6–6.

NOTE: The Inspiratory Time Setting screen displays only if Breath Rate is not OFF or AUTO.

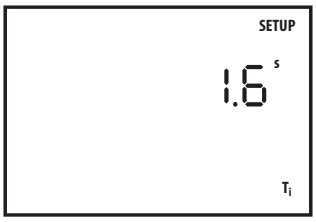


Figure 6–6 Inspiratory Time Setting Screen

Increase or decrease the inspiratory time by pressing the **HEAT** and **RAMP** buttons until the correct setting is reached. You can adjust the inspiratory time from 0.5 to 3 seconds in 0.1 second increments.

NOTE: The inspiratory time and breath rate controls are linked so the inspiratory time never exceeds the expiratory time. If the breath rate or inspiratory time are set to values that would cause the I:E ratio to exceed 1:1, the inspiratory time is automatically reduced to maintain a 1:1 I:E ratio.

6. Rise Time Setting Screen

The Rise Time Setting screen is shown in Figure 6–7. Rise time is the time it takes for the device to change from EPAP to IPAP. This screen allows you to adjust the rise time so you can find the most comfortable setting for the patient.

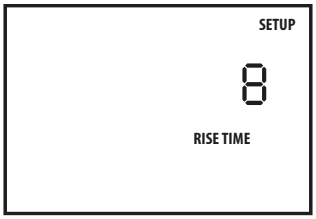


Figure 6–7 Rise Time Setting Screen

NOTE: The Rise Time Setting screen displays only if IPAP Max is greater than EPAP.

Increase or decrease the rise time setting from 1 to 6 by pressing the **HEAT** and **RAMP** buttons until you find the right setting. The rise time of 1 to 6 corresponds to tenths of a second (e.g., a setting of 4 equals 0.4 second rise time).

7. Ramp Length Setting Screen

The Ramp Length Setting screen, shown in Figure 6–8, allows you to change the ramp time.

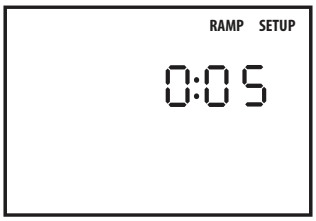


Figure 6–8 Ramp Length Setting Screen

To change the ramp time, press the **HEAT** and **RAMP** buttons until the correct time appears. The setting increases or decreases from 0 to 45 minutes in 5 minute increments. If you do not want ramp, set the time to zero.

NOTE: If the ramp length is set to zero, the ramp settings are complete. Go to step 9.

8. Ramp Start Pressure Setting Screen

The Ramp Start Pressure Setting screen is shown in Figure 6–9.

NOTE: This screen displays only if the ramp length setting is greaterr than 0.

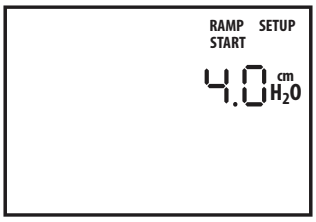


Figure 6–9 Ramp Start Pressure Setting Screen

To change the ramp starting pressure, press the **HEAT** and **RAMP** buttons until the correct pressure appears. The setting increases or decreases in 1.0 cm H_2O increments. The user can adjust the setting from 4 cm H_2O to the current EPAP pressure setting.

9. Apnea Alarm Setting Screen

The Apnea Alarm Setting screen is shown in Figure 6–10. This setting enables or disables the audible alert (a beeping sound) when an apnea is detected.

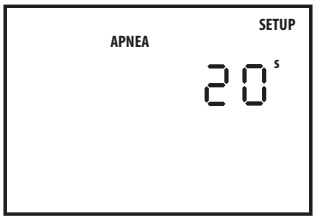


Figure 6–10 Apnea Alarm Setting Screen

Change the apnea alarm setting by pressing the **HEAT** and **RAMP** buttons until the desired setting is reached. You can increase or decrease the time from 0 to 40 seconds in 10 second increments.

- 0 disables the apnea alarm.
- 10 means that the alarm sounds if the time between spontaneous breaths exceeds 10 seconds.
- 20 means that the alarm sounds if the time between spontaneous breaths exceeds 20 seconds.
- 30 means that the alarm sounds if the time between spontaneous breaths exceeds 30 seconds.
- 40 means that the alarm sounds if the time between spontaneous breaths exceeds 40 seconds.

10. Patient Disconnect Alarm Setting Screen

The Patient Disconnect Alarm Setting screen is shown in Figure 6–11.

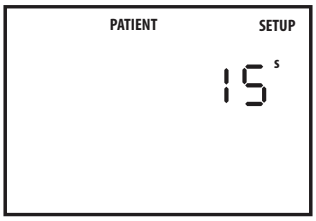


Figure 6–11 Patient Disconnect Alarm Setting Screen

This setting enables or disables the audible alert (a beeping sound) when a large, continuous air leak (such as mask removal) has been detected in the circuit.

To change the patient disconnect alarm setting, press the **HEAT** and **RAMP** buttons until the correct setting appears. You can increase or decrease the setting between 0, 15, and 60 seconds.

- 0 disables the patient disconnect alarm.
- 15 means that the alarm sounds after the patient has been disconnected for 15 seconds.
- 60 means that the alarm sounds after the patient has been disconnected for one minute.

11. Low Minute Ventilation Alarm Setting Screen

The Low Minute Ventilation Alarm Setting screen is shown in Figure 6–12. This setting enables or disables the audible alert (a beeping sound) when a low minute ventilation event is detected.

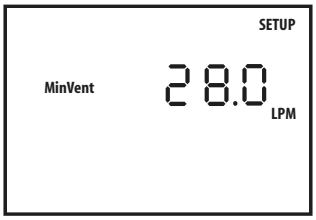


Figure 6–12 Low Minute Ventilation Alarm Setting Screen

Change the alarm setting by pressing the **HEAT** and **RAMP** buttons until the desired setting is reached. You can increase or decrease the setting from 0 to 99 LPM in increments of 1 LPM.

12. Reset Therapy Meter Setting Screen

The Reset Therapy Meter Setting screen is shown in Figure 6–13.

Figure 6–13 Reset Therapy Meter Setting Screen

This screen displays the number of hours that the device delivered therapy to the patient. The decimal point (.) displays if the therapy time is less than 2000 hours. Otherwise, the decimal point does not display so values between 2000 and 19999 hours can display.

To erase the totals and go back to zero, press and hold the **HEAT** or **RAMP** button. **ERASE** displays on the screen. Hold the button down until the time changes to zero and **ERASE** disappears.

13. LED Backlight Setting Screen

The LED Backlight Setting screen is shown in Figure 6–14. This setting allows you to have the lights behind the buttons turned on or off while the airflow is turned on and the device is in the Operate state.

NOTE: The lights will always be on when the airflow is off and the device is in Standby.

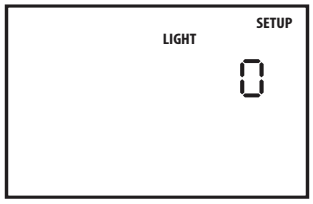


Figure 6–14 LED Backlight Setting Screen

To change the LED backlight setting, press the **HEAT** or **RAMP** button until the correct setting appears. **1** means the lights are on, while **0** means the lights are off.

14. Access Level Setting Screen

The Access Level Setting screen is shown in Figure 6–15.

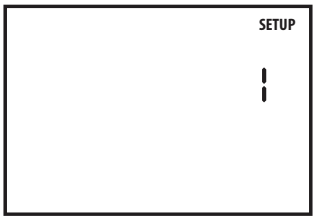


Figure 6–15 Access Level Setting Screen

This screen allows you to select Provider mode or User mode access. Press the **HEAT** and **RAMP** buttons to select the appropriate access level. **0** indicates that the device is in User mode, and **1** indicates that the device is in Provider mode.

This is the last screen in the Provider mode. Press the **SILENCE** button to exit the settings menu or continue pressing the **Right** and **Left User** buttons as shown in Figure 6–1 to navigate to other Provider mode screens.

6.2 Monitoring Measured Parameters

You can view additional measured parameters from the Monitoring screen by pressing the small circular **Scroll** button located near the **RESET** button. Figure 6–16 shows how to navigate the measured parameters screens.

NOTE: You can also view these screens from the Standby screen, but when you do so, each of these screens displays a value of zero because the device is not delivering therapy.

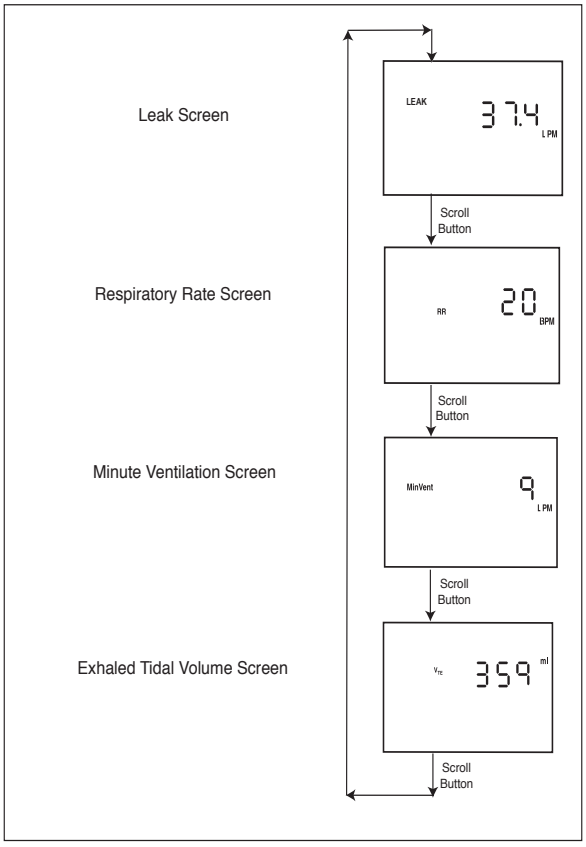


Figure 6–16 Measured Parameter Screen Navigation

To return to the Monitoring or Standby Screen from these Measured Parameter screens, press the **SILENCE** button.

NOTE: The user also has access to these screens.

1. Leak Screen

This screen is shown in Figure 6–17. The Estimated Leak is the average leak value for the last six breaths. The display is updated at the end of each breath.

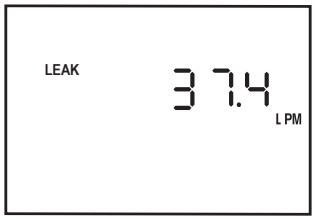


Figure 6–17 Leak Screen

2. **Respiratory Rate Screen**

This screen is shown in Figure 6–18. The Respiratory Rate is the average of the previous six breaths. If the mode supports machine-triggered breaths, this display will be the total breathing rate (spontaneous breaths + machine breaths). The display is updated at the end of each breath.

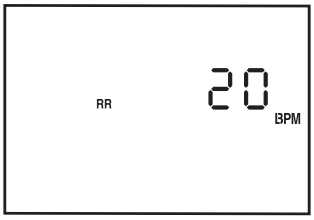


Figure 6–18 Respiratory Rate Screen

3. Minute Ventilation Screen

This screen is shown in Figure 6–19. The estimated Exhaled Minute Ventilation is based on the average of the last six breaths. The display is updated at the end of each breath.

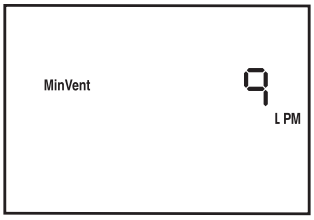


Figure 6–19 Minute Ventilation Screen

NOTE: The value shown for Exhaled Minute Ventilation is an estimate. The display flashes during transient conditions such as low tidal volumes, erratic breathing, or rapidly changing leak.

4. Exhaled Tidal Volume Screen

This screen is shown in Figure 6–20. The estimated Exhaled Tidal Volume is obtained by the integration of patient flow. The display is updated at the end of each breath.

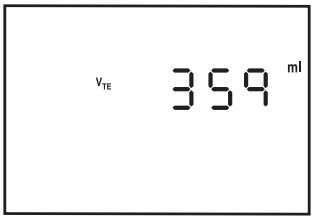


Figure 6–20 Exhaled Tidal Volume Screen

NOTE: The value shown for Exhaled Tidal Volume is an estimate. The display flashes during transient conditions.

6.3 Changing Settings in User Mode

With the device in User mode, the patient is restricted to viewing the following:

- Measured pressure
- Backlight settings
- Humidifier, SmartCard, and ramp status
- Patient alarms
- Measured Parameters (Leak, Respiratory Rate, Minute Ventilation, Exhaled Tidal Volume)

The patient can change the following settings in User mode:

- Humidifier (heat)
- Rise time
- Ramp start pressure
- LED backlight

NOTE: These settings can also be changed when the device is in Provider mode. Detailed instructions for changing these settings are described in Section 6.1.

The figure below shows how to navigate the User mode screens using the **Left** and **Right User** buttons. These screens time out after 60 seconds of inactivity.

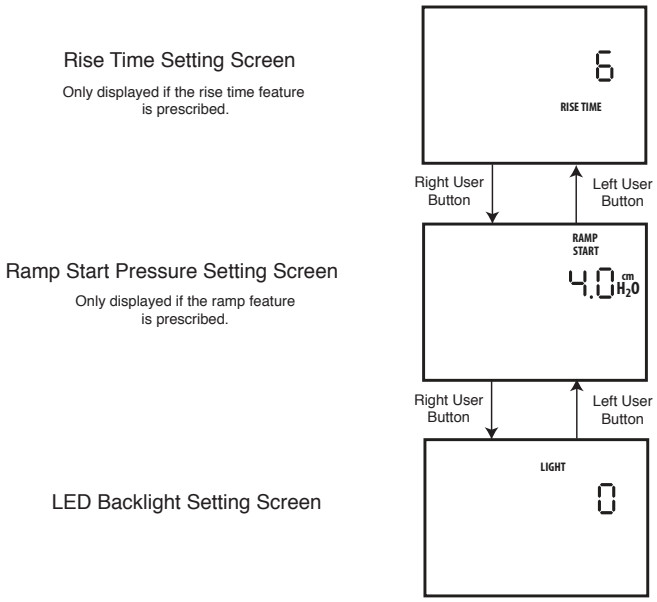


Figure 6–21 Navigating the User Mode Screens

NOTE: When in User mode, **SETUP** does *not* appear in the top right corner of the display.

Chapter 7: Alarms

This chapter describes the device alarms, how to set them, and what corrective actions to take for the alarm conditions.

7.1 Alarm Introduction

The device provides three alarm levels: high, medium, and low priority.

High Priority — These alarms require immediate operator response. The alarm signal consists of a red LED and a high priority sound. The display has **ALARM** at the top of the screen.

Medium Priority — These alarms require prompt operator response. The alarm signal consists of a yellow LED and a medium priority sound. The display has **ALARM** at the top of the screen.

Low Priority — These alarms require operator awareness. The alarm signal consists of a yellow LED and a low priority sound. The display has **ALARM** at the top of the screen.

Some audible alarms are self-cancellable. This means that the alarm sound stops when the cause of the alarm is corrected. See section 7.3 for detailed descriptions of the alarm LEDs and sounds.

Figure 7–1 identifies the alarm LEDs and buttons on the control panel.

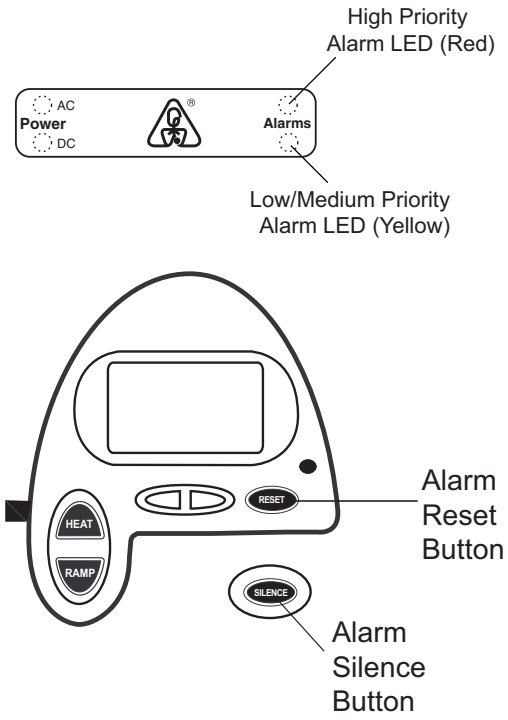


Figure 7–1 Alarm LEDs and Buttons

7.1.1 Overview of Alarm Behavior

Alarm conditions are signalled in three ways: a sound, an LED, and a display message. Each signal type behaves differently depending on the type of alarm.

7.1.1.1 Alarm Sounds Behavior

1. High Priority Sounds

There are two possible high priority sounds:

- **High Priority** – The sound repeats a pattern of three beeps followed by a pause and then two more beeps until the **SILENCE** or **RESET** button is pressed. The silence period is one minute. This pattern is indicated in Section 7.5 as • • • • •
- **Loss of Power** – The sound repeats a pattern of a two-second beep followed by a two-second pause periodically without user intervention. The ⏻ button silences this alarm. The **SILENCE** and **RESET** buttons and the LED control panel backlight do not apply to this alarm. This pattern is indicated in Section 7.5 as ▬ ▬

2. Medium Priority Sound

The medium priority sound repeats a pattern of three beeps every 20 seconds until the **SILENCE** or **RESET** button is pressed. The silence period is one minute. This pattern is indicated in Section 7.5 as • • •

3. Low Priority Sound

The low priority sound repeats a pattern of two beeps every 30 seconds until the **SILENCE** or **RESET** button is pressed. The audible alarm will not reoccur. This pattern is indicated in Section 7.5 as • •

4. Silence Period

The silence period for all applicable alarms is one minute. When the alarm sound is silenced, a flashing LED becomes continuous. If the alarm condition is not corrected by the end of the silence period, the alarm sound is repeated; the LED will flash again. If a new high or medium priority alarm condition occurs during this time, the appropriate LED flashes. New low priority alarms do not cause the LED to flash.

NOTE: Pressing the **SILENCE** button while the silence period is active does not restart the silence period.

7.1.1.2 Alarm LED Behavior

Red Alarm LED The red alarm LED indicates high priority system and patient alarms. The LED flashes when a new high priority alarm is detected. It changes from flashing to continuous when the alarm sound is silenced or the alarm condition is corrected. The LED resumes flashing when the silence period expires or if a new alarm occurs. The LED turns off when all high priority alarms with an automatic reset method end and there are no high priority alarms with a manual reset method active. Additionally, the red LED turns off when you press the **RESET** button.

NOTE: A continuous red LED indicates a loss of power or a silenced high priority alarm.

Yellow Alarm LED The yellow alarm LED indicates medium or low priority system and power alarms. The LED flashes when a new medium priority alarm is detected. It changes from flashing to continuous when the alarm sound is silenced or if the alarm condition is corrected. The LED resumes flashing when the silence period expires or if a new alarm occurs. The LED turns off when all medium and low priority alarms with an automatic reset method end and there are no medium or low priority alarms with a manual reset method active. Additionally, the yellow alarm LED turns off when you press the **RESET** button.

7.1.1.3 Display Behavior

For high, medium, and low priority alarms, the display shows **ALARM** and the error code or name of the alarm.

7.2 System Alarms

The device has several system alarms:

- System Errors
- Card Errors
- Pressure Regulation High
- Pressure Regulation Low
- Low Pressure Support
- Prescription Card Complete

7.2.1 System Error Alarm

The System Error alarm is a high priority alarm. It indicates that there is a problem with the device. Unlike other high priority alarms, the red LED cannot be turned off because the alarm does not stop until the power shuts down and is then restored.

A System Error screen is shown in Figure 7–2.

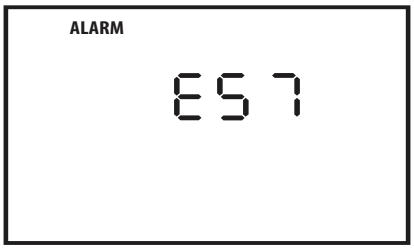


Figure 7–2 System Error Screen

A three digit error code displays on the screen, indicating the type of error (e.g., error code 57 displays as E57). A complete list of system error codes can be found in Appendix A. When a system error occurs, the device's LCD backlight is turned on and the blower and humidifier are off. Pressing the **RESET** button only shuts off the audible alarm.

7.2.2 Card Error Alarm

The SmartCard Error alarm is a low priority alarm. It indicates that a problem exists with the card inserted in the SmartCard connectivity slot. Removing the SmartCard automatically resets this alarm. Additionally, pressing the **RESET** button stops the alarm until another invalid SmartCard is inserted and detected.

The Card Error screen is shown in Figure 7–3.

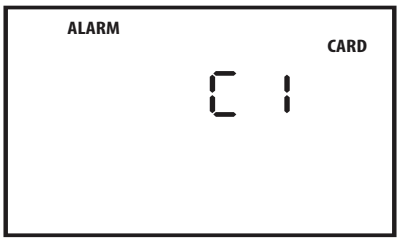


Figure 7–3 Card Error Screen

An error code and **CARD** displays on the screen, indicating the type of error (e.g., error code 1 displays as C1). A complete list of SmartCard error codes can be found in Appendix A. When a card error occurs, the device's LCD backlight is turned on. Pressing either the **SILENCE** or **RESET** button exits this screen and returns to the previous screen.

7.2.3 Pressure Regulation High Alarm

The Pressure Regulation High alarm is a high priority alarm. It indicates that the outlet pressure is greater than 5 cm H_2O above the current IPAP setting. This alarm does not reset automatically. Press the **RESET** button to manually reset this alarm.

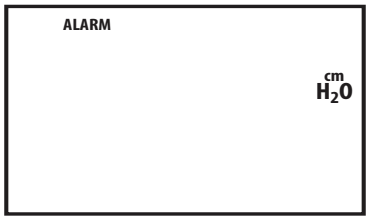


Figure 7–4 Screen for Pressure Regulation High Alarm, Pressure Regulation Low Alarm, and Low Pressure Support Alarm

NOTE: The Pressure Regulation High Alarm, Pressure Regulation Low Alarm, and Low Pressure Support Alarm all display the same screen.

When this screen displays a Pressure Regulation High alarm, the **cm H_2O** and **ALARM** flash and the LCD backlight is turned on. Pressing either the **SILENCE** or **RESET** button exits this screen and returns to the previous screen.

7.2.4 Pressure Regulation Low Alarm

The Pressure Regulation Low alarm is a high priority alarm that indicates when the patient is not receiving adequate pressure therapy (the outlet pressure is 5 cm H_2O below the current IPAP setting). This alarm does not reset automatically. Press the **RESET** button to manually reset this alarm.

Figure 7–4 shows the screen that appears when a Pressure Regulation Low alarm occurs. This screen is identical to the Pressure Regulation High alarm or Low Pressure Support alarm screens. When this screen displays a Pressure Regulation Low alarm, the **cm H_2O** and **ALARM** flash and the LCD backlight is turned on. Pressing either the **SILENCE** or **RESET** button exits this screen and returns to the previous screen.

7.2.5 Low Pressure Support Alarm

The Low Pressure Support alarm is a high priority alarm that indicates that a low pressure support condition has been detected for 60 seconds. This alarm does not reset automatically. Press the **RESET** button to manually reset this alarm.

Figure 7–4 shows the screen that appears when a Low Pressure Support alarm occurs. This screen is identical to the Pressure Regulation High (or Low) alarm screens. The **cm H_2O** and **ALARM** flash and the LCD backlight is turned on. Pressing either the **SILENCE** or **RESET** button exits this screen and returns to the previous screen.

7.2.6 Prescription Complete Alarm

Figure 7–5 shows the screen that appears when a Prescription Complete alarm occurs.

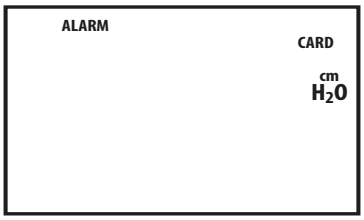


Figure 7–5 Prescription Complete Alarm Screen

If a prescription-only SmartCard is inserted in the device and is successfully written to the device, **CARD**, **cm H_2O** and **ALARM** flash and a low priority audible alert sounds. Press the **RESET** button to reset the alarm.

Remove the SmartCard from the device to exit this screen and return to the previous screen.

7.3 Patient Alarms

The device has the following patient alarms:

- Apnea
- Patient Disconnect
- Low Minute Ventilation

7.3.1 Apnea Alarm

Figure 7–6 shows the alarm screen.

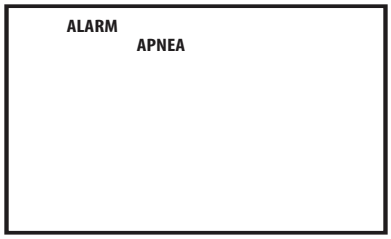


Figure 7–6 Apnea Alarm Screen

The Apnea alarm is a high priority alarm that detects the cessation of spontaneous breathing. It occurs when the time between spontaneous breaths exceeds the Apnea alarm time setting (10, 20, 30, or 40 seconds). See Chapter 6 for information on how to set the Apnea alarm time.

When an apnea alarm occurs, **APNEA** and **ALARM** flash on the display and the LCD backlight is turned on.

NOTE: A setting of zero disables the Apnea alarm.

This alarm does not automatically reset. Press the **RESET** button to manually reset the alarm.

7.3.2 Patient Disconnect Alarm

Figure 7–7 shows the alarm screen.

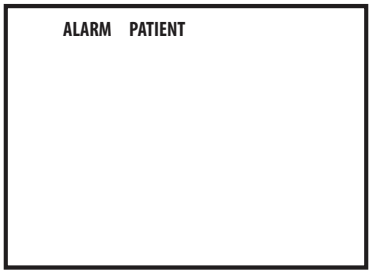


Figure 7–7 Patient Disconnect Alarm Screen

The Patient Disconnect alarm is a high priority alarm. It occurs when the patient is disconnected from the device for the time specified in the Patient Disconnect alarm time setting (0, 15, or 60 seconds). See Chapter 6 for information on how to set the Patient Disconnect alarm time.

When a patient disconnect alarm occurs, **PATIENT** and **ALARM** flash on the display and the LCD backlight is turned on.

NOTE: A setting of zero disables the Patient Disconnect alarm.

This alarm does not automatically reset. Press the **RESET** button to manually reset the alarm.

7.3.3 Low Minute Ventilation Alarm

Figure 7–8 shows the alarm screen.

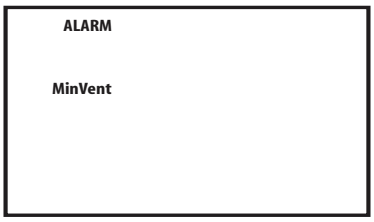


Figure 7–8 Low Minute Ventilation Alarm Screen

The Low Minute Ventilation alarm is a high priority alarm. It occurs when the calculated minute ventilation is less than or equal to the alarm setting. See Chapter 6 for information on how to set the Low Minute Ventilation alarm time.

When a Low Minute Ventilation alarm occurs, **ALARM** and **MinVent** flash on the display and the LCD backlight is turned on.

NOTE: A setting of zero disables the Low Minute Ventilation alarm.

This alarm does not automatically reset. Press the **RESET** button to manually reset the alarm.

7.4 Power Alarms

The device has the following power alarms:

External Battery Discharged — This alarm occurs when the external battery is below 9.8 V. This alarm does not occur if AC power is available, but the Low External Battery alarm remains active. The red alarm LED is solid when this alarm occurs and the power failure audible alarm beeps. The **SILENCE** and **RESET** buttons do not apply to this alarm.

Loss of Input Power — This alarm occurs when AC and DC power is lost while the device is in the Operate state, or AC and DC power is not available when the ⏻ button is pressed. The red alarm LED is solid when this alarm occurs and the power failure audible alarm beeps. The **SILENCE** and **RESET** buttons do not apply to this alarm.

Low External Battery — This alarm occurs when the external battery is below 10.3 V. It is a medium priority alarm. When this alarm occurs, the yellow LED and the DC power LED flash upon detection. When the alarm is reset or the battery is replaced, the yellow LED goes away and the DC power LED stops flashing (but remains on to indicate that DC power is being used). The medium priority audible alarm sounds. This alarm automatically resets when the external battery is replaced. Additionally, you can press the **RESET** button to reset this alarm; however, the alarm will reoccur unless the external battery is replaced.

AC to DC Power Switchover — This alarm occurs when the device switches from AC to DC power. It is a low priority alarm. When this alarm occurs, the yellow LED and the DC power LED flash upon detection. When the alarm is reset, the yellow LED goes away and the DC power LED stops flashing (but remains on to indicate that DC power is being used). The low priority audible alarm sounds. This alarm automatically resets when AC power is restored. Additionally, you can use the **RESET** button to manually reset this alarm.

Battery in Use — This alarm occurs only upon startup, to notify the user that battery power is being used. This is a low priority alarm. When this alarm occurs, the yellow LED turns on and the DC power LED flashes upon detection and stops when AC power is provided or the alarm is reset. The low priority audible alarm sounds. This alarm automatically resets when AC power is provided. Press the **RESET** button to manually reset this alarm.

AC Power Supply — This alarm may indicate two issues, depending on which power supply is connected. If only the DC power adapter is connected, the alarm indicates that the power supply has a defective battery sense line. If only the AC power supply is connected of if both the AC power supply and DC power adapter are connected, this alarm indicates that the AC power supply is out of specification (less than 22 V). Press the **RESET** button to reset the alarm. However, the AC power LED continues to flash after a manual reset.

7.5 Alarm Summary Tables

The following tables summarize the patient, system, and power alarm information.

Patient Alarms

Alarm	LED Indicator	Display Message	Audible Indicator	Device Action	Possible Cause	Patient Action	Provider Action
Apnea	Red flash	**ALARM** and **APNEA** flash	• • • • •	Operates	Apnea event occurred during therapy.	Press the **RESET** button to reset the alarm. Report the alarm to your health care professional. Continue using your device.	Verify patient status.
Patient Disconnect	Red flash	**ALARM** and **PATIENT** flash	• • • • •	Operates	Patient circuit is disconnected or has a large leak.	Press the **RESET** button to reset the alarm. Reconnect the patient circuit or correct the leak. If the alarm continues, contact your health care professional.	Reconnect the patient circuit or fix the leak. If the alarm continues, contact an authorized service representative or Respironics to have the device serviced.
Low Minute Ventilation	Red flash	**ALARM** and **MinVent** flash	• • • • •	Operates	The calculated minute ventilation is less than or equal to the alarm setting.	Press the **RESET** button to reset the alarm. Report the alarm to your health care professional. Continue using your device.	Verify patient status.

System Alarms

Alarm	LED Indicator	Display Message	Audible Indicator	Device Action	Possible Cause	Patient Action	Provider Action
System Error	Red flash	**ALARM** flashes and system error code ("Exx") displays	• • • • •	Shuts down and blower cannot be restarted.	Device failure.	Press the **RESET** button to reset the alarm. Remove power from the device. Restore power. If the alarm continues to occur, contact your health care professional.	Have the device serviced by either an authorized service representative or Respironics.
Card Error	Yellow solid	**CARD** flashes and card error code ("Cxx") displays	• •	Operates	A problem exists with the Smart Card inserted in the SmartCard connectivity slot. The card may be inserted upside down or backwards.	Press the **RESET** button to reset the alarm. Confirm that the card is properly inserted. If the alarm continues to occur, remove the SmartCard from the device and contact your health care professional.	Confirm that the card is properly inserted. If the alarm continues, replace the SmartCard.
Pressure Regulation High	Red flash	**ALARM** and **cm H_2O** flash	• • • • •	If the condition occurs for 0.5 seconds, the unit cycles to EPAP. After 3 seconds, if the condition continues, a high priority alarm is generated, but the unit still operates. If the condition is still detected after 10 seconds, the unit shuts down.	Malfunctioning device.	Remove power from the device. Restore power. If the alarm continues to occur, call your health care professional.	Have the device serviced by either an authorized service representative or Respironics.
Pressure Regulation Low	Red flash	**ALARM** and **cm H_2O** flash	• • • • •	Operates	Excessive leak or blockage.	Press the **RESET** button to reset the alarm. Check for the following: dirty inlet filters, blocked air intake, excessive leak in patient circuit. If alarm continues, call your health care professional.	Check for the following: dirty inlet filters, blocked air intake, excessive leak in patient circuit. If the alarm continues, have the device serviced by either an authorized service representative or Respironics.
Low Pressure Support	Red flash	**ALARM** and **cm H_2O** flash	• • • • •	Operates	Excessive leak or blockage.	Press the **RESET** button to reset the alarm. Check for the following: dirty inlet filters, blocked air intake, excessive leak in patient circuit. If alarm continues, call your health care professional.	Check for the following: dirty inlet filters, blocked air intake, excessive leak in patient circuit. If the alarm continues, have the device serviced by either an authorized service representative or Respironics.
Prescription Complete	Yellow solid	**ALARM**, **CARD** and **cm H_2O** flash	• •	Operates	Prescription SmartCard has been inserted into the device.	Press the **RESET** button to reset the alarm. Remove the SmartCard from the device.	Remove the SmartCard to exit this screen and return to the previous screen.

Power Alarms

Alarm	LED Indicator	Display Message	Audible Indicator	Device Action	Possible Cause	Patient Action	Provider Action
External Battery Discharged*	Red solid	Blank screen	■ ■	Shuts down	The external battery is below 9.8 V.*	Press the ⏻ button to silence the alarm. Remove DC power source from the device and replace the battery to restore power. Or, seek a reliable AC power source.	Replace the battery.
Loss of Input Power	Red solid	Blank screen	■ ■	Shuts down	Power was lost while the device was providing therapy.	Press the ⏻ button to silence the alarm. Restore power. If the alarm continues to occur, contact your health care professional.	Restore power to the device. If the alarm continues to occur, have the device serviced by either an authorized service representative or Respironics.
Low External Battery*	Yellow alarm LED flashes DC power LED flashes		• • •	Operates	Battery is nearly discharged (below 10.3 V).*	Press the **RESET** button to reset the alarm. Replace or recharge the battery. If the alarm continues to occur, contact your health care professional.	Replace the battery. If the alarm continues to occur, have the device serviced by either an authorized service representative or Respironics.
AC to DC Power Switchoff	Yellow solid DC power LED flashes		• •	Operates	The device loses AC power and switches to DC power.	Press the **RESET** button to reset the alarm. Check AC power. Seek a reliable power source.	None required.
Battery in Use	Yellow solid DC power LED flashes		• •	Operates	On startup only, alarm notifies the user that battery power is being used.	Press the **RESET** button to reset the alarm.	None required.
AC Power Supply*	Yellow alarm LED solid AC power LED flashes	Unchanged	• •	Operates	The AC power supply is out of spec (<22V) or there is a defective battery sense line on the DC power adapter.	Remove power from the device and then restore power. If alarm continues to occur, contact your health care professional.	Have the power supply serviced by Respironics or an authorized service representative.

*Measured at the external DC power adapter inlet.

Chapter 8: Cleaning and Maintenance

8.1 Cleaning the Device

WARNING: To avoid electrical shock, always unplug the device power cord from the wall outlet or DC power source before cleaning the device.

WARNING: Do not immerse the device in liquid or allow any liquid to enter the enclosure, inlet filter, or any opening. This may result in equipment damage.

1. Unplug the device and clean the front panel and exterior of the enclosure as needed using a cloth dampened with water and a mild detergent. Allow the device to dry completely before plugging in the power cord.
2. Inspect the device and all circuit parts for damage after cleaning. Replace any damaged parts.

WARNING: To clean breathing circuit accessories, refer to the cleaning instructions for each accessory.

8.1.1 Cleaning and Disinfection for Multiple Users

WARNING: If you are using the device on multiple users, discard and replace the bacteria filter each time the device is used on a different person.

If you are using the device on multiple users, complete the following steps to clean and disinfect the device before each new user.

1. Unplug the device before disinfecting.
2. Disinfect the outside of the device only. Use a cloth with one of the following cleaning agents to clean the exterior of the device: Hydrogen Peroxide, 3%; 100% Isopropyl Alcohol; Vinegar, 5% acidity; Water; Chlorine bleach, household, 5.25% sodium hypochloride, 1 to 5 part reduction with water
3. Allow the device to dry completely before plugging in the power cord.

8.2 Cleaning or Replacing the Inlet Filters

The device uses two removable filters at the air inlet. The gray foam filter is washable and reusable. The optional white ultra-fine filter is disposable. Under normal usage, clean the gray foam filter at least once every two weeks and replace it with a new one every six months.

CAUTION: Dirty inlet filters may cause high operating temperatures that may affect performance. Regularly examine the inlet filters as needed for integrity and cleanliness.

1. If the device is operating, stop the airflow by pressing the ⏻ button. Disconnect the device from the power source.
2. Remove the filter cap by gently pressing in on the sides of the filter cover and pulling the cap out, away from the device. (Figure 8–1).

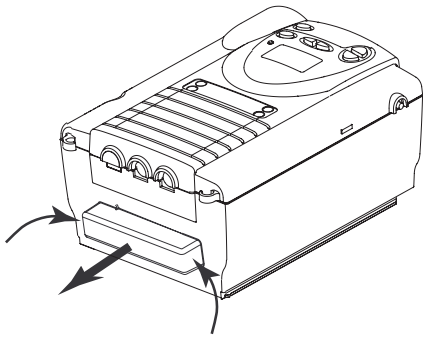


Figure 8–1 Removing the Filter Cover

3. Remove the filters from the enclosure by gently pulling around the edges of the filters. The top filter is the reusable gray foam filter. The bottom filter is the optional disposable white ultra-fine filter (Figure 8–2).

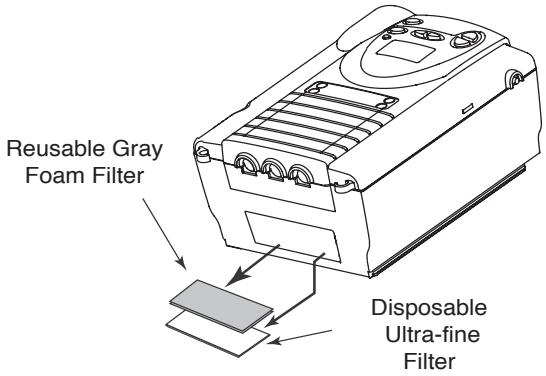


Figure 8–2 Removing the Filters

4. Examine the filters regularly for cleanliness and integrity.
5. If needed, wash the gray foam filter in warm water with a mild detergent. Rinse thoroughly to remove all detergent residue. Allow the filter to dry completely before reinstalling it. If the foam filter is torn, replace it. (Only Respironics-supplied filters should be used as replacement filters.)

CAUTION: Never install a wet filter into the device. It is recommended that you clean the filter in the morning and alternate using the two gray foam filters provided with the system to ensure sufficient drying time for the cleaned filter.

6. If the ultra-fine filter is dirty or torn, replace it.
7. Reinstall the filters. If you are using the optional white ultra-fine filter, place it against the gray foam filter so the soft side of the ultra-fine filter touches the gray foam filter. Slide the filters into the air inlet at the rear of the device and push them into the recess. When the filters are installed, the hard plastic side of the white filter will touch the inside of the device.
8. Reinstall the filter cover.

8.3 Maintenance

See the BiPAP autoSV Service Manual for recommended periodic maintenance.

WARNING: Electrical cords or cables should be periodically inspected for damage or signs of wear.

8.4 Carrying Case

A carrying case (reorder number: 1005965) is included with your BiPAP autoSV system. The case is designed to hold your device, along with your circuit accessories and humidifier.

When you are travelling, the carrying case can be used for carry-on luggage only. The carrying case will not protect the device if it is put through checked baggage.

NOTE: If travelling with your humidifier, make sure you empty the water chamber before placing it in the carrying case.

Chapter 9: Adding Supplemental Oxygen

Oxygen may be added at the mask connection. Please note the warnings listed below when using oxygen with the device.

WARNING: The oxygen supply must comply with local regulations for oxygen use.

WARNING: When using oxygen with this system, a Respironics Pressure Valve (Part number 302418) must be placed in-line with the patient circuit. Place the valve in-line with the patient circuit and connect the oxygen as shown here:

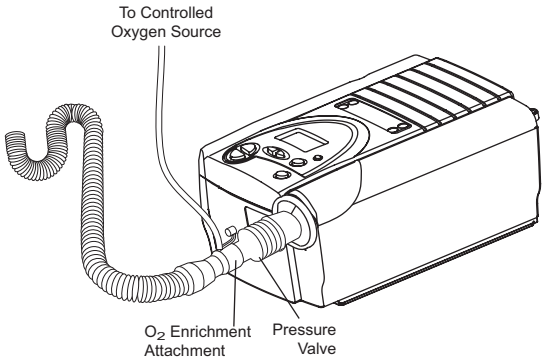


Figure 9–1 Using the Respironics Pressure Valve

WARNING: Oxygen should be administered only on the order of a physician.

WARNING: Supplemental oxygen should not be added to the breathing circuit by placing the source where the gas will be entrained through the inlet filter on the rear of the device.

WARNING: Continuous patient monitoring is recommended while administering oxygen. Patient monitoring should consist of, at a minimum, patient observation and pulse oximetry. Arterial blood gas measurements should be used when necessary.

WARNING: If administering fixed-flow supplemental oxygen, the oxygen concentration may not be constant. The inspired oxygen concentration will vary, depending on the current IPAP pressure and EPAP setting, patient breathing pattern, and the leak rate. Substantial leaks around the mask may reduce the inspired oxygen concentration to less than the expected concentrations shown in section 9.2. Appropriate patient monitoring should be implemented.

WARNING: When using oxygen with this system, turn the device *on* before turning the oxygen on. Turn the oxygen *off* before turning the device off. This will prevent oxygen accumulation in the device.

WARNING: Oxygen accelerates fires. Keep the device and the oxygen container away from heat, open flames, any oily substance, or other sources of ignition. **Do not** smoke in the area near the device or the oxygen.

9.1 Adding Supplemental Oxygen

The delivered oxygen concentration varies with changes in flow in the circuit. The following may have an impact on oxygen concentration:

- Pressure settings
- Patient Tidal Volume
- Peak Inspiratory Flow
- I:E Ratio
- Respiratory rate
- Circuit leak rate
- Oxygen flow rate

To add oxygen to the circuit, the oxygen supply must comply with the local regulations for medical oxygen. The oxygen flow into the patient circuit cannot exceed 15 L/min and the pressure cannot exceed 50 psi.

9.2 Supplemental Oxygen Concentrations

Figures 9–2 and 9–3 illustrate the potential range of oxygen concentration available to the patient at a given tidal volume, supplemental oxygen flow, and pressure setting. These figures represent bench test results without inadvertent mask leaks when oxygen is administered at the mask. Substantial leaks around the mask may reduce the expected oxygen concentration to below the levels shown in Figures 9–2 and 9–3. This guideline may be used as a starting point for initiating oxygen therapy. Oxygen flow should be gradually adjusted until the patient's oxygen needs are adequately met.

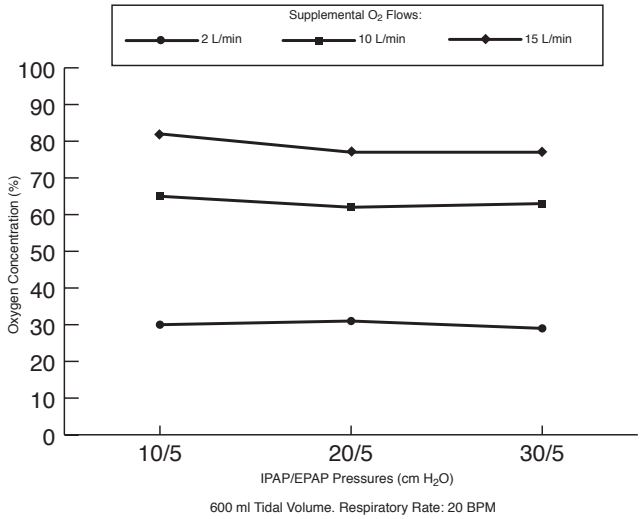


Figure 9–2 Oxygen Concentration for 600 ml Tidal Volume

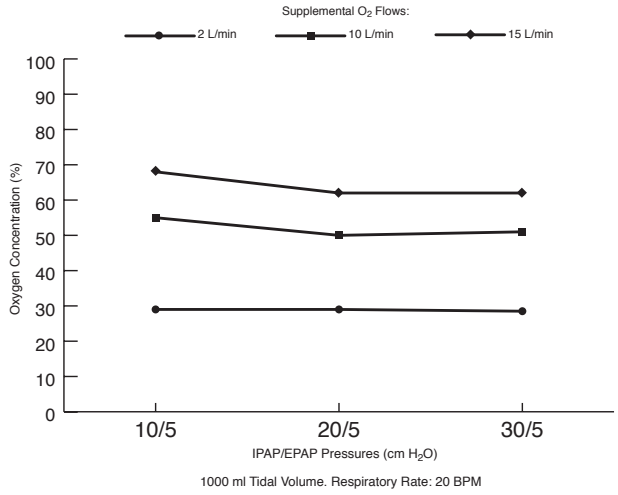


Figure 9–3 Oxygen Concentration for 1000 ml Tidal Volume

Chapter 10: Circuits and Accessories

This chapter details the Respironics-approved breathing circuit and accessories.

WARNING: Refer to each accessory's instruction sheet for the applicable warnings, cautions, and notes.

10.1 Circuit Configurations

WARNING: The device requires an intentional leak port, either built into the mask or on a separate exhalation device (e.g., Whisper Swivel II, Plateau Exhalation Valve (PEV), or Disposable Exhalation Valve) to remove exhaled air from the circuit. Therefore, specific masks and circuits using an intentional leak port are required for normal operation. The pressurized air from the device causes a continuous flow of air to exhaust from the leak port to flush the exhaled air from the circuit. The device should be turned on and the intentional leak port should be checked before using the device.

The device is intended for use with Respironics-approved patient circuits. Typical components are:

- Bacteria filter (optional)
- 22 mm reusable circuit tubing
- Exhalation device
- Respironics patient interface (e.g., mask)
- Respironics Pressure Valve (Part Number 302418, required), if adding supplemental oxygen
- Humidifier (optional)

Additional accessories may be added to the circuit to meet specific needs.

10.2 Circuits and Accessories

1. Reusable or Disposable Circuit
   - Reusable smooth inner lumen circuit tubing and exhalation port
   - Disposable smooth inner lumen circuit tubing and exhalation port
2. Circuit Accessories
   - 6 in. (15.2 cm) disposable circuit tubing
   - 18 in. (45.7 cm) disposable circuit tubing
   - 72 in. (182.9 cm) disposable circuit tubing
   - O_2 enrichment attachment
   - Bacteria filter
3. Accessories
   - DC power adapter
   - Respironics Communication cable
   - Remote alarm

10.3 Masks, Exhalation Ports, and Related Accessories

1. Masks
    - Respironics mask with built-in exhalation port or Respironics mask with separate exhalation device
2. Accessories
    - Disposable headgear
    - Reusable headgear
    - Chin strap

10.4 Humidifiers

1. Respironics REMstar Heated humidifier
2. Respironics Pass-over humidifier
3. Respironics H2 Heated humidifier

NOTE: Refer to the humidifier's instructions for information on how to set up the BiPAP autoSV device with the humidifier.

10.5 Software

Respironics Encore® Pro Data Management software for reading compliance data.

CHAPTER 11: OPERATIONAL VERIFICATION

WARNING: If the system fails to perform within the specifications stated in Chapter 12, have the system serviced by a qualified Respironics-approved service facility.

11.1 SYSTEM VERIFICATION

The operational verification allows health care professionals to verify that the device is functioning properly. Operational verification should be completed before each new patient setup.

1. Connect the 6.35 mm BiPAP test orifice to the outlet port.
2. Connect a water column or digital manometer to the pressure pick-off port on the test orifice.
3. Connect the AC power supply to the device and connect the AC power cord to the appropriate power source. If the device being tested is an international device, test the device at the voltage for that specific country. The AC power LED should illuminate.
4. Access the Provider mode.
5. Set the parameters to the following:
   - EPAP = 4 cm H_2O
   - IPAP Min = 30 cm H_2O
   - IPAP Max = 30 cm H_2O
   - Rate = Auto
   - Rise Time = 1
   - Ramp = 0 (Off)
   - Patient Disconnect = 0 (Off)
   - Apnea = 0 (Off)
   - Low Minute Ventilation = 0 (Off)

   Exit to the Monitoring screen.
6. Press the ⏻ button to turn the airflow on and put the device in the Operate state.
7. Occlude the outlet of the device for 4 seconds, and then open the outlet for 4 seconds. Do this several times while observing the manometer reading and the device display.
   - Verify that the screen agrees with the pressure indicated on the manometer.
8. To verify the performance of the patient alarms, see Section 11.2.

11.2 Alarm Verification

Keep the test orifice and parameter setups as used in the system verification described in Section 11.1.

Patient Disconnect Alarm Test

1. Set the Apnea Alarm setting to 0 (Off).
2. Set the Patient Disconnect Alarm setting to 15 sec.
3. Exit to the Monitoring screen. Remove the test orifice.
   - Verify that the Patient Disconnect Alarm occurs in approximately 15 seconds.
4. Press the **SILENCE** button to silence the alarm, and wait for one minute until the alarm sounds again.
5. Press the **RESET** button to clear the alarm.
6. Replace the test orifice.
7. Simulate a breathing pattern by occluding and opening the outlet port to correct the alarm condition.

NOTE: The red high priority alarm indicator light will appear solid when the alarm condition has subsided, or if the alarm has been silenced. The light will remain solid until the alarm has been cleared.

8. Set the Patient Disconnect Alarm setting to 0 (Off).

Apnea Alarm Test

9. Set the Apnea Alarm setting = 10 sec.
10. Exit to the Monitoring screen. Simulate breathing by alternately occluding and opening the outlet port; then occlude the outlet port.
    - Verify that the Apnea alarm occurs in approximately 10 seconds.
11. Press the **RESET** button to clear the alarm.
12. Set the Apnea Alarm setting to 0 (Off).

Low Minute Ventilation Alarm Test

13. Simulate 6 breaths by alternately occluding and opening the outlet port for 2 seconds each.
14. Set the Low Minute Ventilation Alarm setting = 10.0 LPM.
15. Simulate 1 or 2 breaths by occluding and opening the outlet port.
    - Verify that the Low Minute Ventilation alarm occurs.
16. Set the Low Minute Ventilation Alarm setting to 0.0 (Off).

Loss of Input Power Alarm Test

17. While the device is still operating, disconnect the power cord from the device.
    - Verify that a Loss of Input Power alarm sounds.
    - Reconnect power to stop the alarm.

IMPORTANT When testing is complete, and before patient use, adjust the device to the appropriate patient settings.

CHAPTER 12: SPECIFICATIONS

ENVIRONMENTAL

	Operating	Storage
Temperature	41° F (5° C) to 95° F (35° C)	-4° F (-20° C) to 140° F (60° C)
Relative Humidity	15 to 95% (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure (5600 feet to sea level)	83 to 102kPa	

PHYSICAL

Dimensions:	9.75 in. L x 6.625 in. W x 4.4 in. H (24.8 cm L x 16.8 cm W x 11.2 cm H)
Weight:	4 lbs (1.8 kg)

ELECTRICAL

AC Voltage Source:	100 to 240 VAC, 50/60 Hz
DC Voltage Source:	12 VDC (when operated with the external DC power adaptor accessory)
AC Current:	1.25 A maximum
DC Current:	3.0 A maximum
Protection against electric shock:	Class II
Degree of protection against electric shock:	Type BF Applied Part
Degree of protection against harmful ingress of water:	
BiPAP autoSV device:	Ordinary Equipment, IPX0
AC Power Supply (Reorder number 1012832):	Drip Proof, IPX1
DC Power Adapter (Reorder number 1012975):	Drip Proof, IPX1
Modes of Operation:	Continuous
Electromagnetic Compatibility:	The BiPAP autoSV device meets the requirements of EN 60601-1-2, second edition (2001).
Fuses:	There are no user-replaceable fuses.

PRESSURE

Output:	4 to 30 cm H_2O

Control Accuracy

Parameter	Range	Accuracy
IPAP Min	4 to 30 cm H_2O	± 5 cm H_2O*
IPAP Max	4 to 30 cm H_2O	± 5 cm H_2O*
EPAP	4 to 25 cm H_2O	± 5 cm H_2O*
Breath Rate	4 to 30 BPM	Greater of ± 1 BPM or ± 10% of the setting (when measured over a 4 minute period)
Timed Inspiration	0.5 to 3.0 seconds	± (0.1 + 10% of the setting) seconds
Ramp Duration	0 to 45 minutes	± 10% of the setting
Rise Time	1 to 6 **	± 25%***

* Dynamic pressure accuracy is ± 5 cm H_2O measured at the patient end of the circuit with a Whisper Swivel II and varying flow conditions. Static pressure accuracy is ± 2 cm H_2O measured at the patient end of the circuit with a Whisper Swivel II and no patient flow.

** The range of values correspond to tenths of seconds (e.g., a setting of 4 indicates a Rise Time of 0.4 seconds).

*** Measured at the patient end of circuit with a Whisper Swivel II exhalation device and no patient flow.

Measured Parameter Accuracy

Parameter	Accuracy
Respiratory Rate	Greater of ±1 BPM or ±10% of reading when measured over a four minute period
Exhaled Tidal Volume	± (25 + 0.15 of reading) ml
Exhaled Minute Ventilation	± (1 + 0.15 of reading) L/min
Leak Rate	± (5 + 0.15 of reading) L/min

Triggers and Cycles

Patient Inspired Volume: 6 ml

Spontaneous Trigger:
- Shape Trigger
- Volume 6 ml above Vleak

Spontaneous Cycle:
- Spontaneous Expiratory Threshold (SET)
- IPAP Maximum of 3.0 seconds

Connector

The patient interface port is a 22 mm tapered connector.

Disposal

Dispose of this device in accordance with local regulations.

Pressure Drop Versus Flow for Patient Circuits

The device automatically compensates for pressure drops associated with a 6-foot (182.9 cm) smooth bore tube. Additional pressure drops will occur when restrictive elements are added to the patient circuit. The following graph shows the additional pressure drop when adding:

1. A bacteria filter

2. A bacteria filter and a Respironics Pass-over humidifier

NOTE: Always use a manometer to verify patient mask pressure.

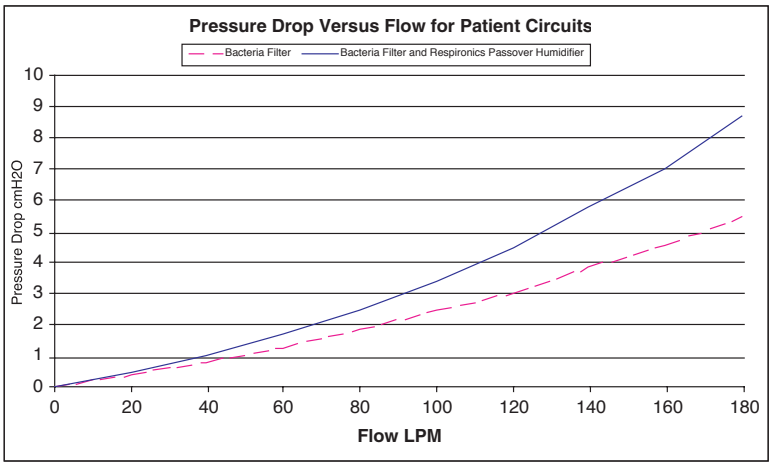


Figure 12–1 Pressure Drop Versus Flow for Patient Circuits

Maximum Pressure Drop for Patient Disconnect Alarm

The Patient Disconnect alarm relies on a fixed relationship between the patient pressure settings and the open circuit flow of the patient circuit. The alarm should work properly if your circuit is less restrictive than the circuit parameters shown below.

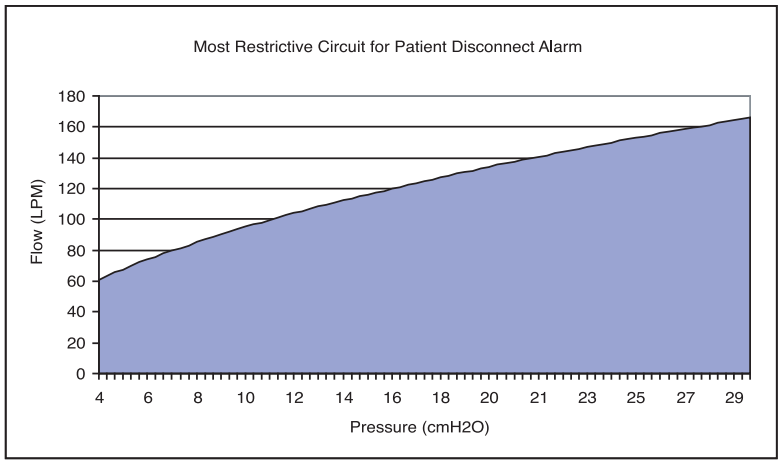


Figure 12–2 Most Restrictive Circuit for Patient Disconnect

NOTE: You must verify that the Patient Disconnect Alarm operates properly with the prescribed patient pressures and circuit.

Appendix A: Error Codes

This appendix lists the definitions for the displayed error codes. For more information about each error and how to service the device, see the BiPAP autoSV Service Manual.

SYSTEM ERRORS

Display	Description	Provider/User Action
E0	No error	For all system errors ("Exx"), perform the following actions: • Remove power from the device. • Restore power. • If the error continues to occur, call Respironics or an authorized service representative to have the device serviced.
E1	Generic software error	
E2	Software corrupt	
E3	External RAM failure	
E4	FIQ Stack Overflow	
E5	FIQ Stack Underflow	
E6	Nested IRQ Stack Overflow	
E7	Nested IRQ Stack Underflow	
E8	IRQ Stack Overflow	
E9	IRQ Stack Underflow	
E10	Timer Stack Overflow	
E11	Timer Stack Underflow	
E12	Service Stack Overflow	
E13	Service Stack Underflow	
E14	Thread Stack Overflow	
E15	Undefined Instruction	
E16	Unexpected Software Interrupt	
E17	Microprocessor Prefetch Exception	
E18	Data Access Exception	
E19	Reserved Exception	
E20	Spurious Default Interrupt	
E21	Spurious Interrupt	
E22	Corrupt calibration table	
E23	Invalid zero flow value in calibration table	
E24	Unrecognized version of calibration table	
E25	Excessive drift on flow sensor	
E26	Communications failure with LCD driver chip	
E27	Excessive drift on outlet pressure sensor	
E28	Empty calibration table	
E29	Excessive drift on blower pressure sensor	
E30	Unrecognized version of parameter storage	

E31	Un-repairable parameter storage
E32	Corrupt parameter storage
E33	Excessive parameter storage size
E34	Unable to queue data to parameter storage
E35	Unable to write to parameter storage
E36	Parameter out of range in parameter storage
E37	Corrupt real-time clock value
E38	Real-time clock not ticking
E39	Unable to queue data to user interface
E40	Invalid Built-in Self Test call
E41	Over pressure condition
E42	Operating system not responding to software
E43	Insufficient voltage for audible alarm
E44	12V reference out of range
E45	5V reference out of range
E46	Bulk voltage out of range
E47	–15V reference out of range
E48	Railed Flow sensor
E49	Blower pressure sensor failure
E50	Reserved for future use
E51	Unrecognized Main PCA
E52	Blower failure
E53	Blower speed out of tolerance
E54	Motor current high while blower off
E55	Buffer overflow
E56	Motor current high while blower on
E57	Unable to queue data to provide therapy
E58	Stuck key
E59	Outlet pressure sensor railed
E60	Blower pressure sensor railed

E61	Real-time clock's battery is dead
E62	Blower speed exceeded max
E63	Internal watchdog failure
E64	External watchdog failure
E65	Unexpected watchdog reset
E66	Reserved for future use
E67	Operating system failed initialization
E68	Unable to queue data for communications
E69	Sampling thread locked
E70	Execution thread locked
E71	Internal RAM failure
E72	Unable to queue data for logging
E73	Reserved for future use
E74	Reserved for future use
E75	Reserved for future use
E76	Failure in loss of power battery
E77	High pressure condition
E78	Low pressure condition
E79	Unable to maintain pressure support
E80	Barometric pressure sensor failure
E81	Barometric pressure sensor out of range
E82	Rise rate range failure
E83	Invalid array index failure
E84	Reserved for future use
E85	Reserved for future use
E86	Reserved for future use
E87	Occluded flow sensor
E88	Invalid error code

CARD ERRORS

Display	Description	Provider/User Action
C1	Unable to write to SmartCard.	The SmartCard is inserted upside-down or backwards. Remove the card and reinsert properly. Otherwise, the card is damaged and should be replaced.
C2, C3	The SmartCard is corrupt or not supported by this device.	Perhaps the card is intended for another device. Erase or reprogram the card. If the error continues to occur, replace the card.
C4	The SmartCard contains a prescription and was inserted while the device was in a parameter screen.	Remove the card. Exit the parameter screen. Then reinsert the card.
C5	The SmartCard was inserted while the device was in calibration mode.	Remove the card. Exit the calibration mode. Then reinsert the card.
C6	The SmartCard is corrupt.	Erase or reprogram the card. If the error continues to occur, replace the card.
C7	SmartCard presence lost.	Remove card and reinsert. Otherwise, the card is damaged and should be replaced.
C8	Unable to read from the SmartCard.	The card is inserted upside-down. Remove the card and reinsert properly. Otherwise, the card is damaged and should be replaced.
C9, C10, C100, C101	The SmartCard is corrupt.	Erase or reprogram the card. If the error continues to occur, replace the card.
C103 - C105	The SmartCard contains an unknown prescription.	The SmartCard contains a prescription that is not supported by this device. Perhaps the card is intended for another device.
C106 - C109, C200	The SmartCard is corrupt.	Erase or reprogram the card. If the error continues to occur, replace the card.
C201	The SmartCard contains an unknown logging format.	The card contains a logging format that is not supported by this device. Perhaps the card is intended for another device.
C202 – C207 C300 - C303 C400 - C414 C500 - C506	The SmartCard is corrupt.	Erase or reprogram the card. If the error continues to occur, replace the card.

Appendix B: EMC Information

Guidance and Manufacturer's Declaration - Electromagnetic Emissions: This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity: This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity: This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey **a**, should be less than the compliance level in each frequency range **b**. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b: Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device: The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Limited Warranty

Respironics, Inc. warrants that the BiPAP autoSV system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace – at its option – the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

Respironics, Inc. disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. In addition, any implied warranties – including any warranty of merchantability or fitness for the particular purpose – are limited to two years. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To exercise your rights under this warranty, contact your local authorized Respironics, Inc. dealer or contact Respironics, Inc. at:

1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550
1-724-387-4000

RESPIRONICS®

1001 Murry Ridge Lane
Murrysville, PA 15668
USA

Respironics Deutschland
Gewerbestrasse 17
82211 Herrsching, Germany

CE 0123

1040272
JR 3/1/07